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(54) **PERCUTANEOUS SPINAL IMPLANTS AND METHODS**

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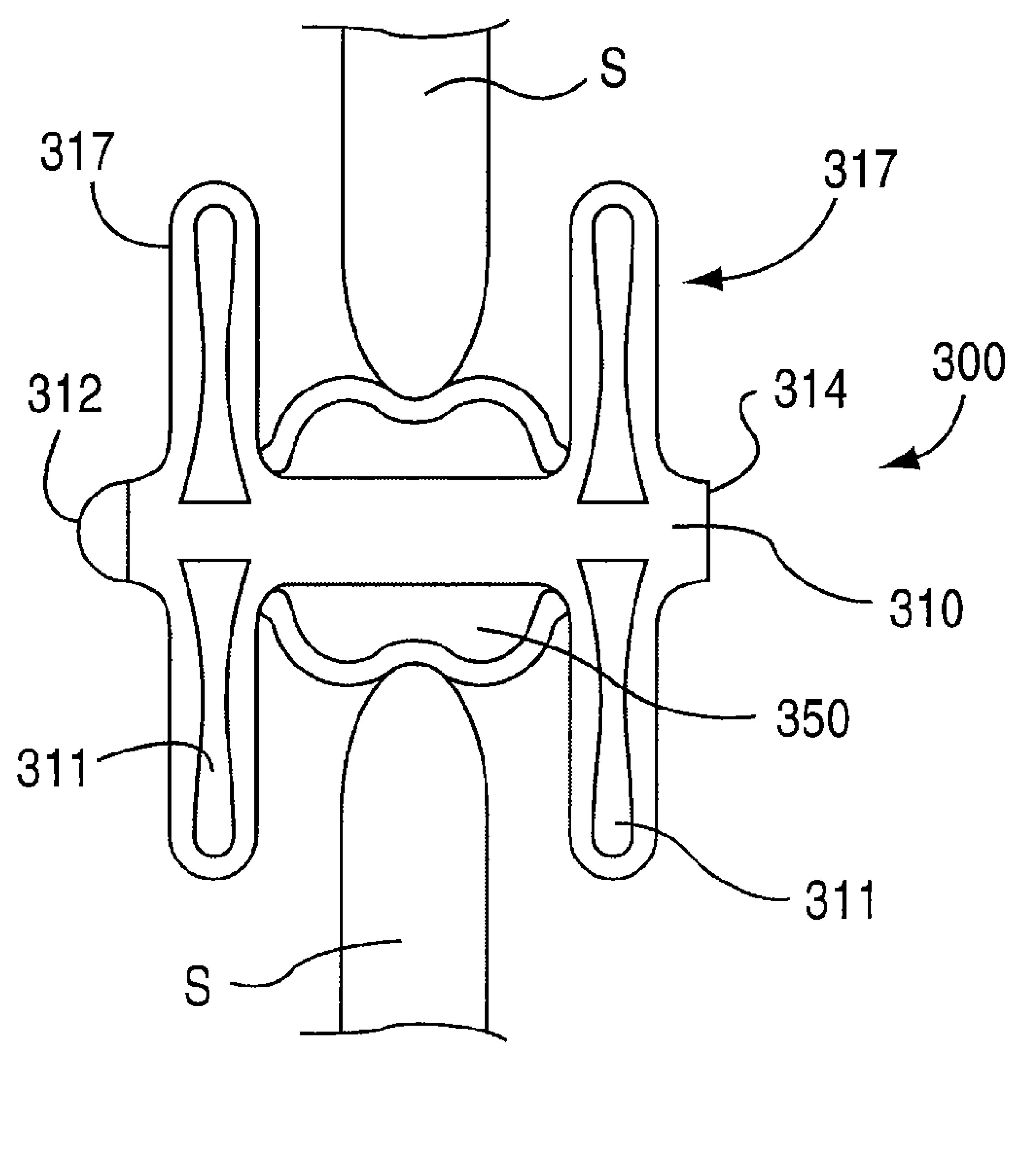
(57) **ABSTRACT**

A method includes positioning a medical device within a body between adjacent spinous processes, moving the medical device from a collapsed configuration to an expanded configuration within the body using an actuator removably coupled to the medical device, and removing the actuator from the body while the medical device remains between the adjacent spinous processes.

22 Claims, 82 Drawing Sheets



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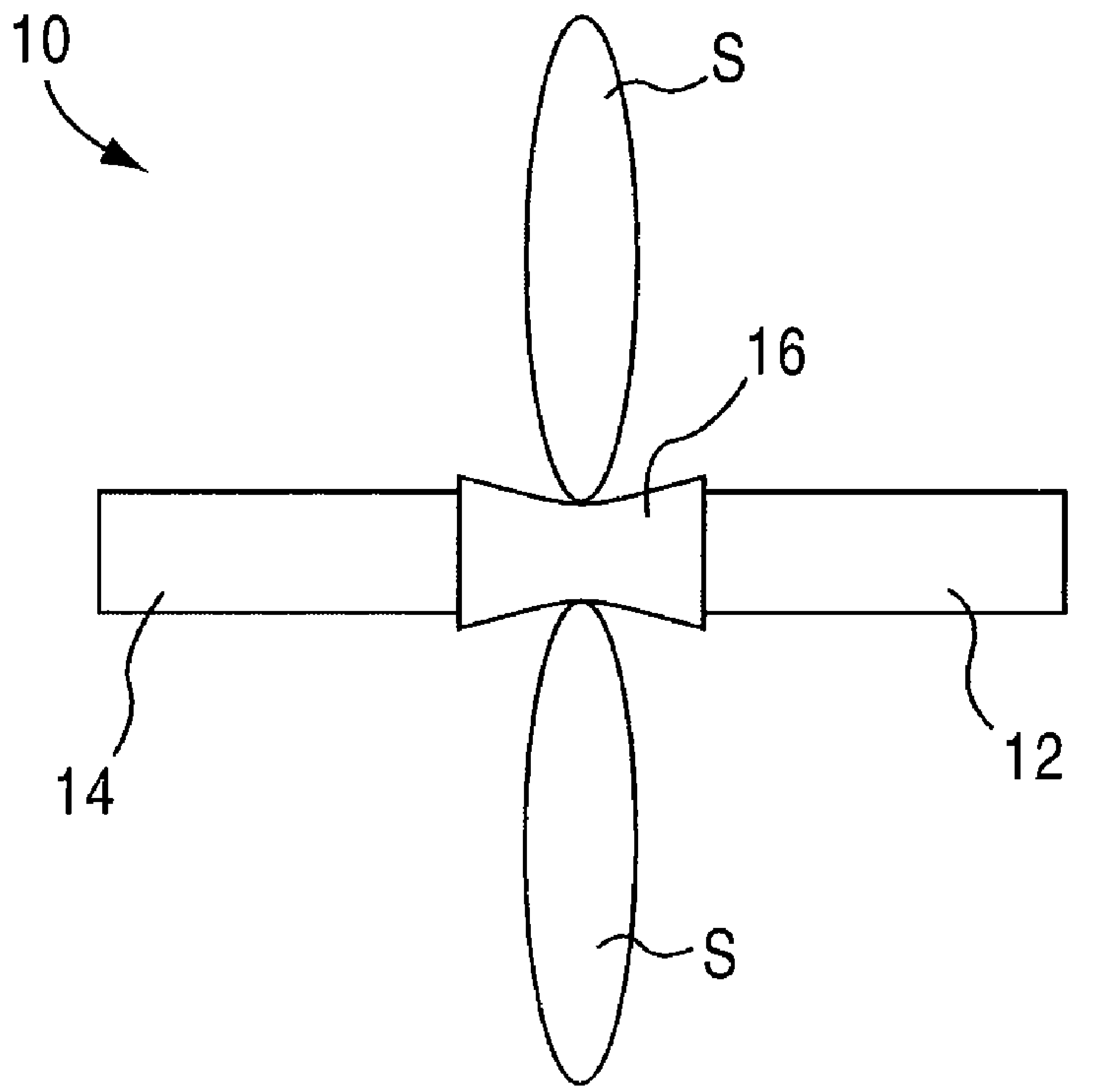


FIG. 1

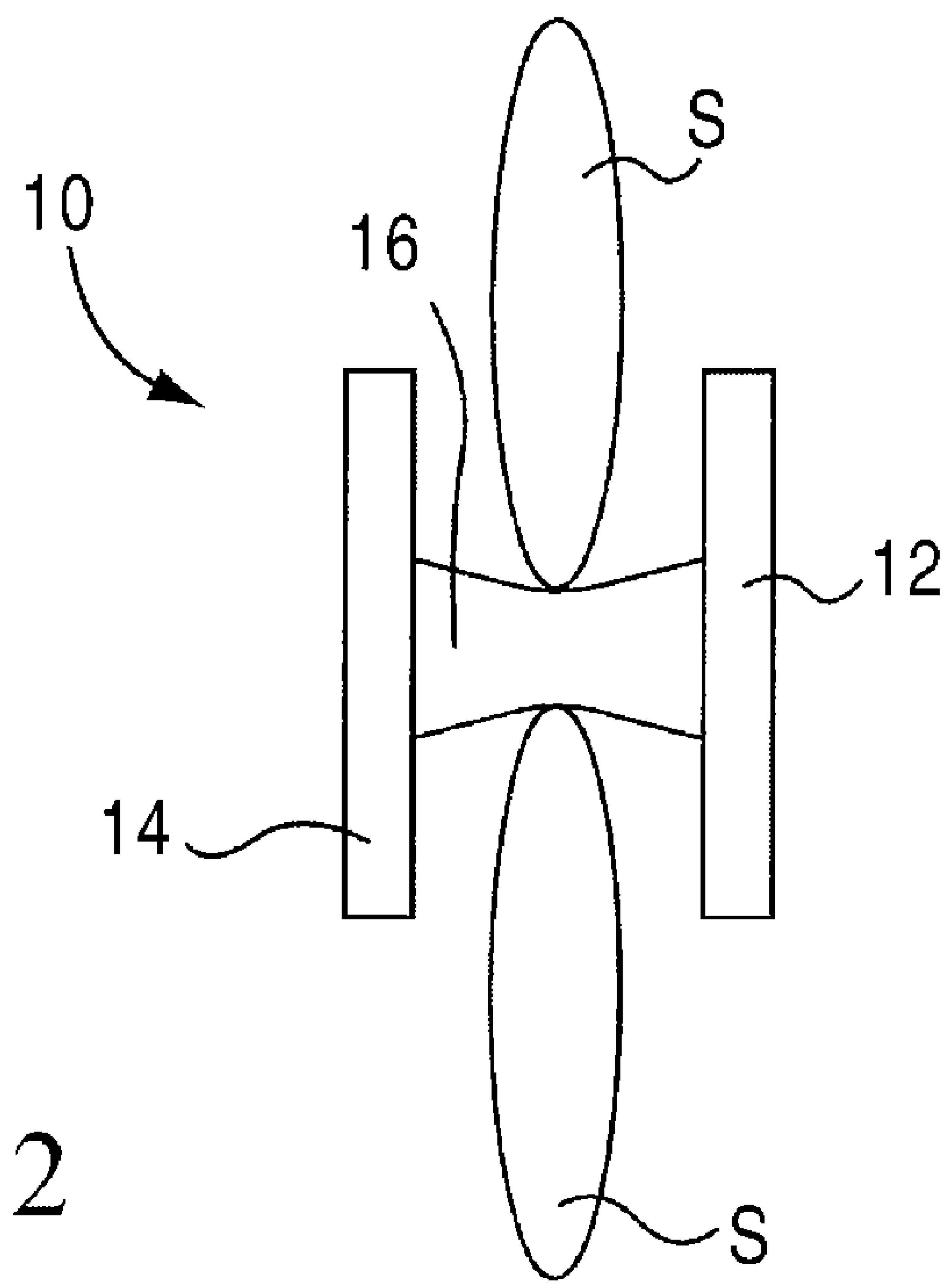


FIG. 2

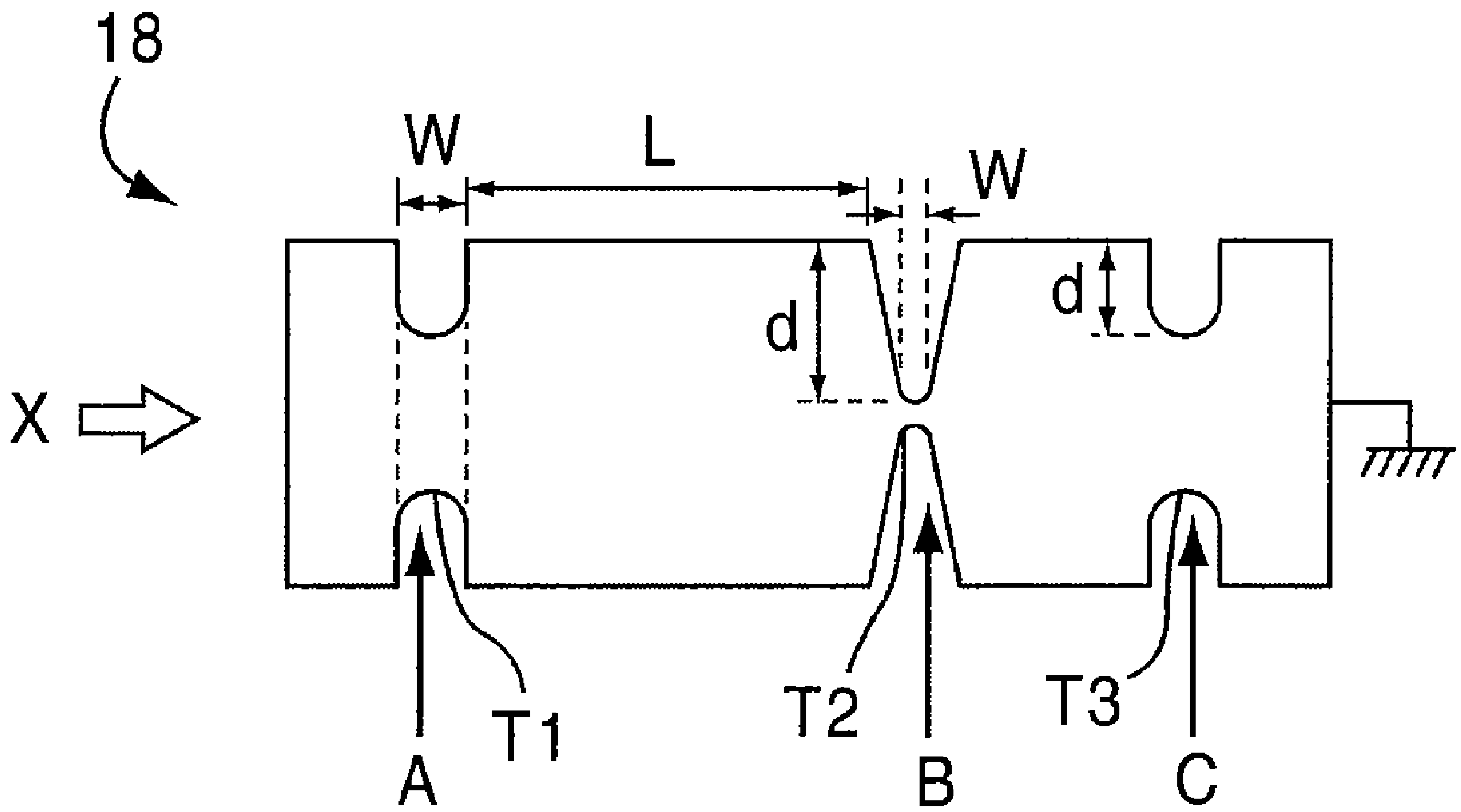


FIG.3

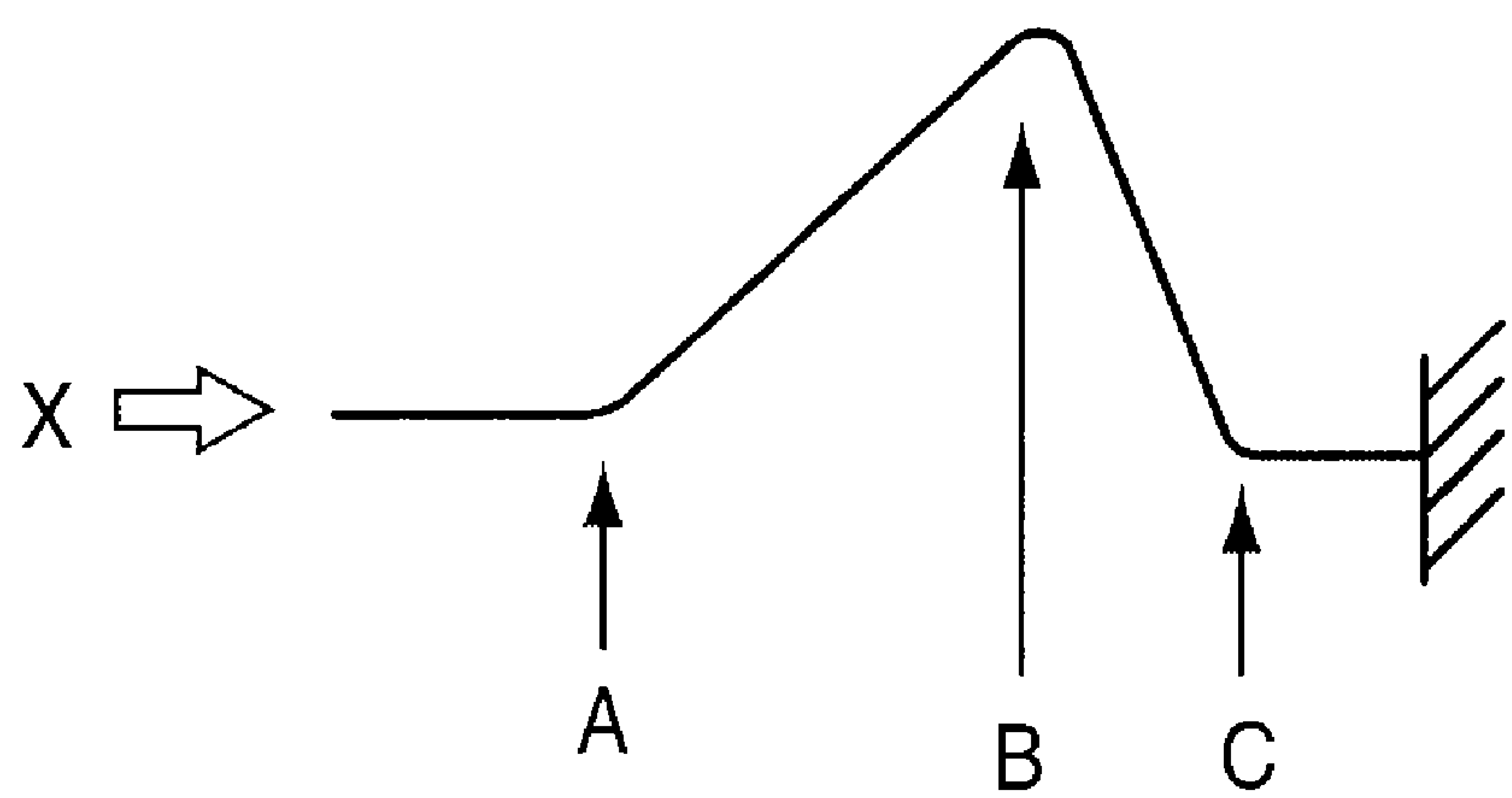


FIG.4

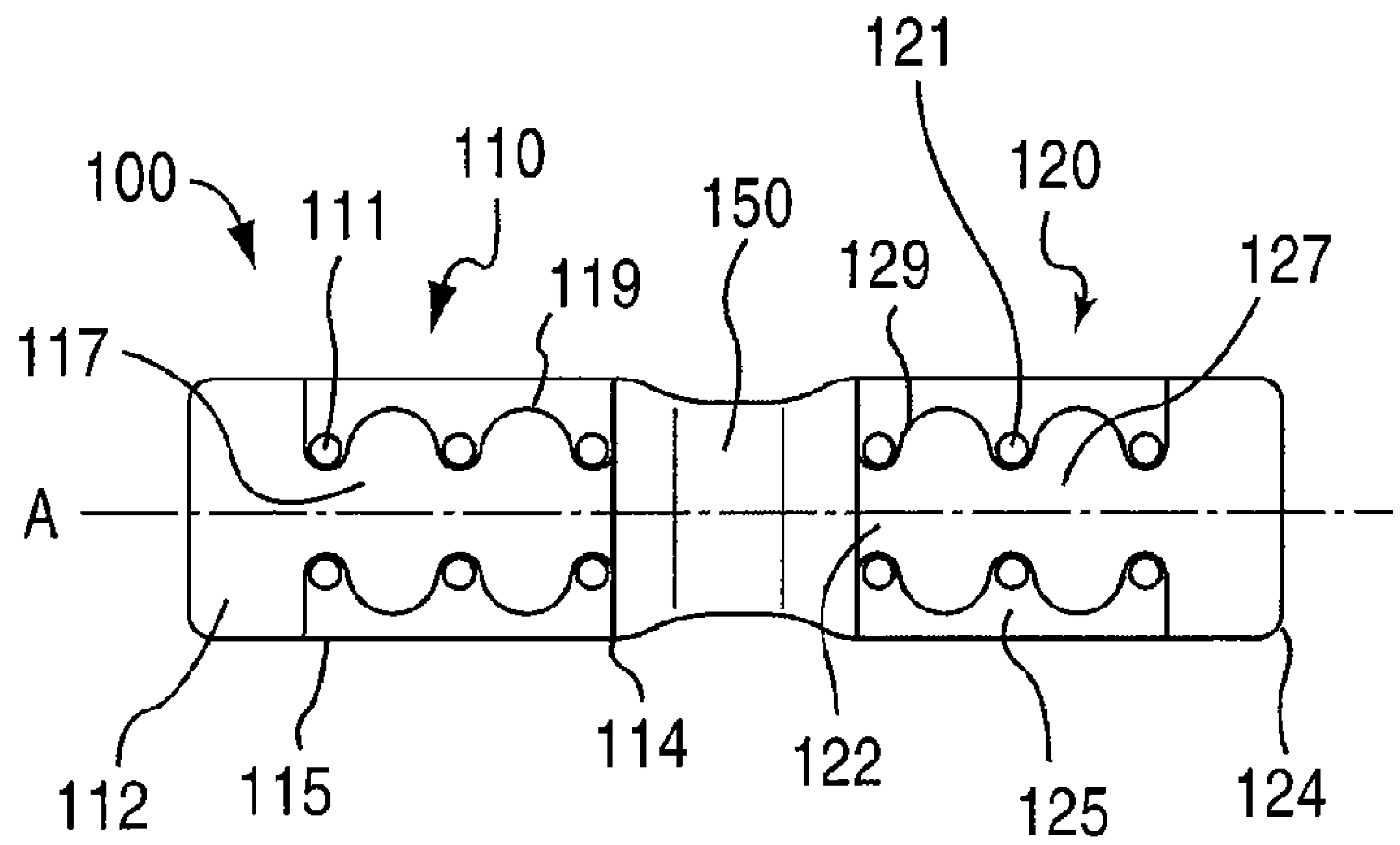


FIG.5

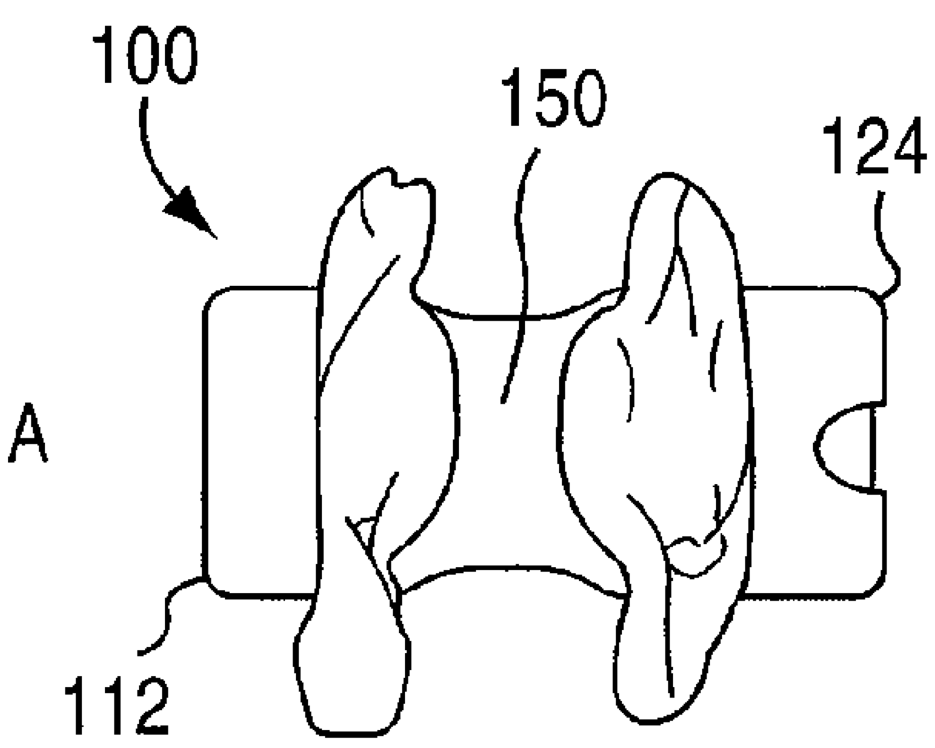


FIG.6

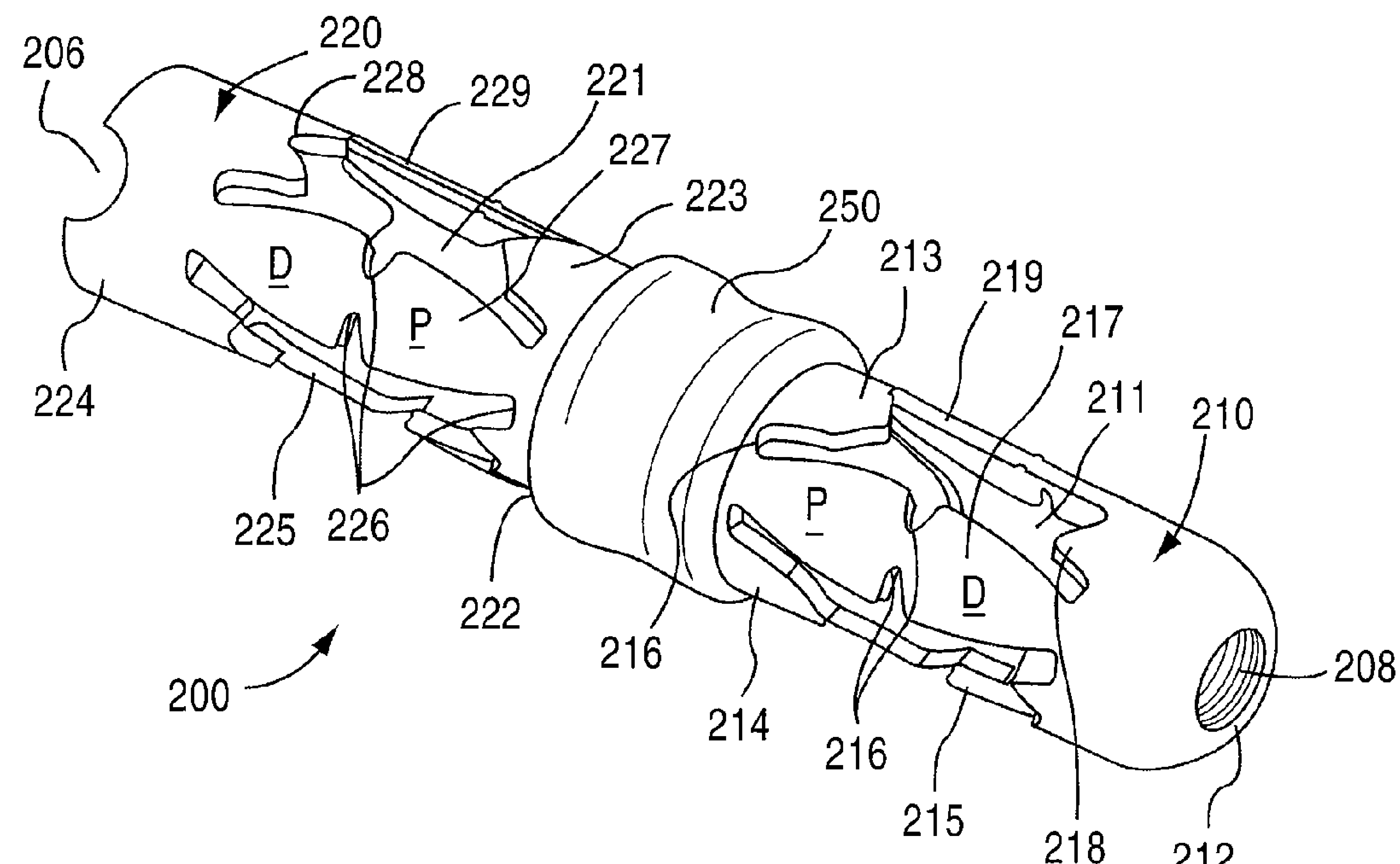


FIG.7

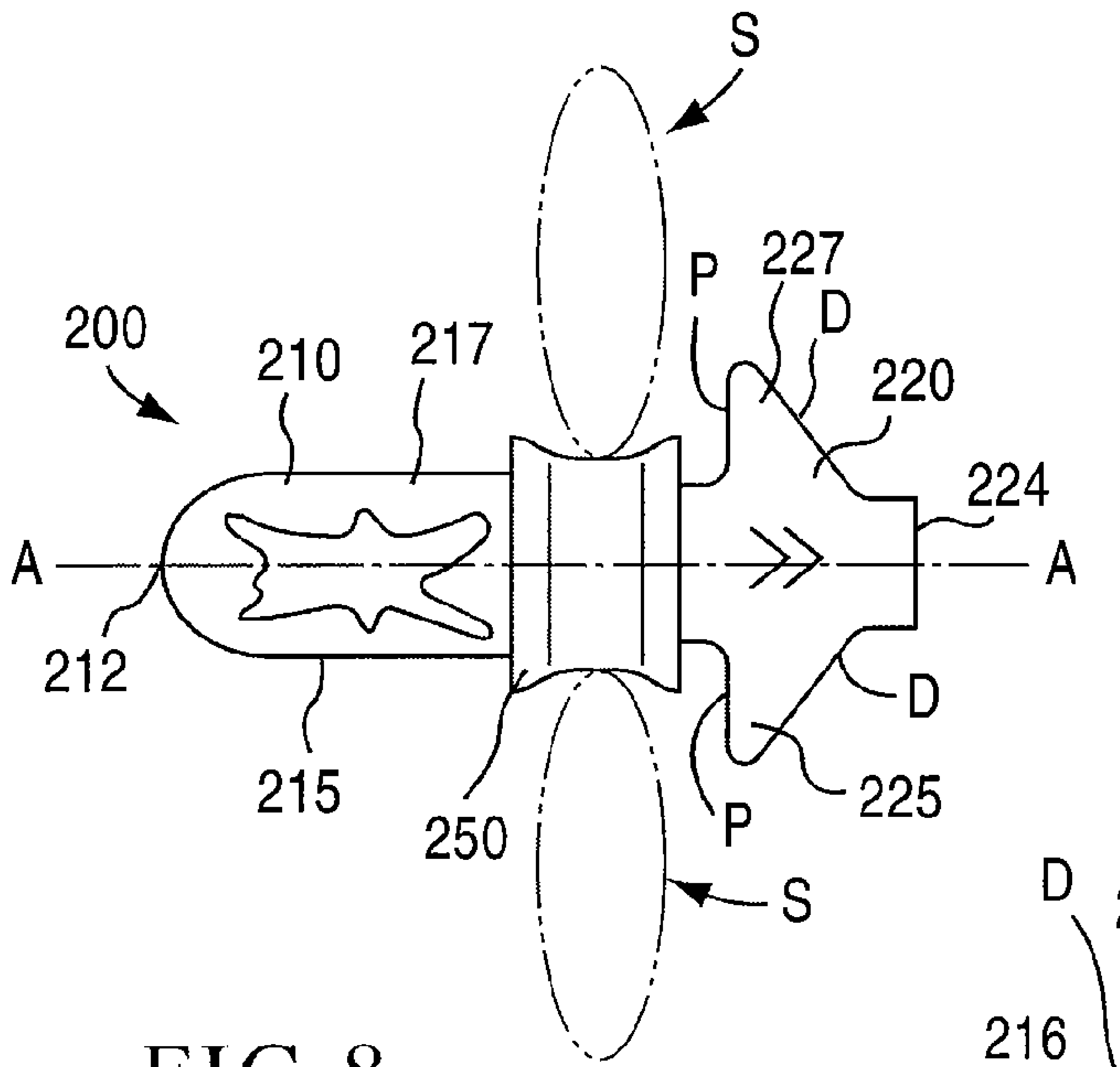


FIG.8

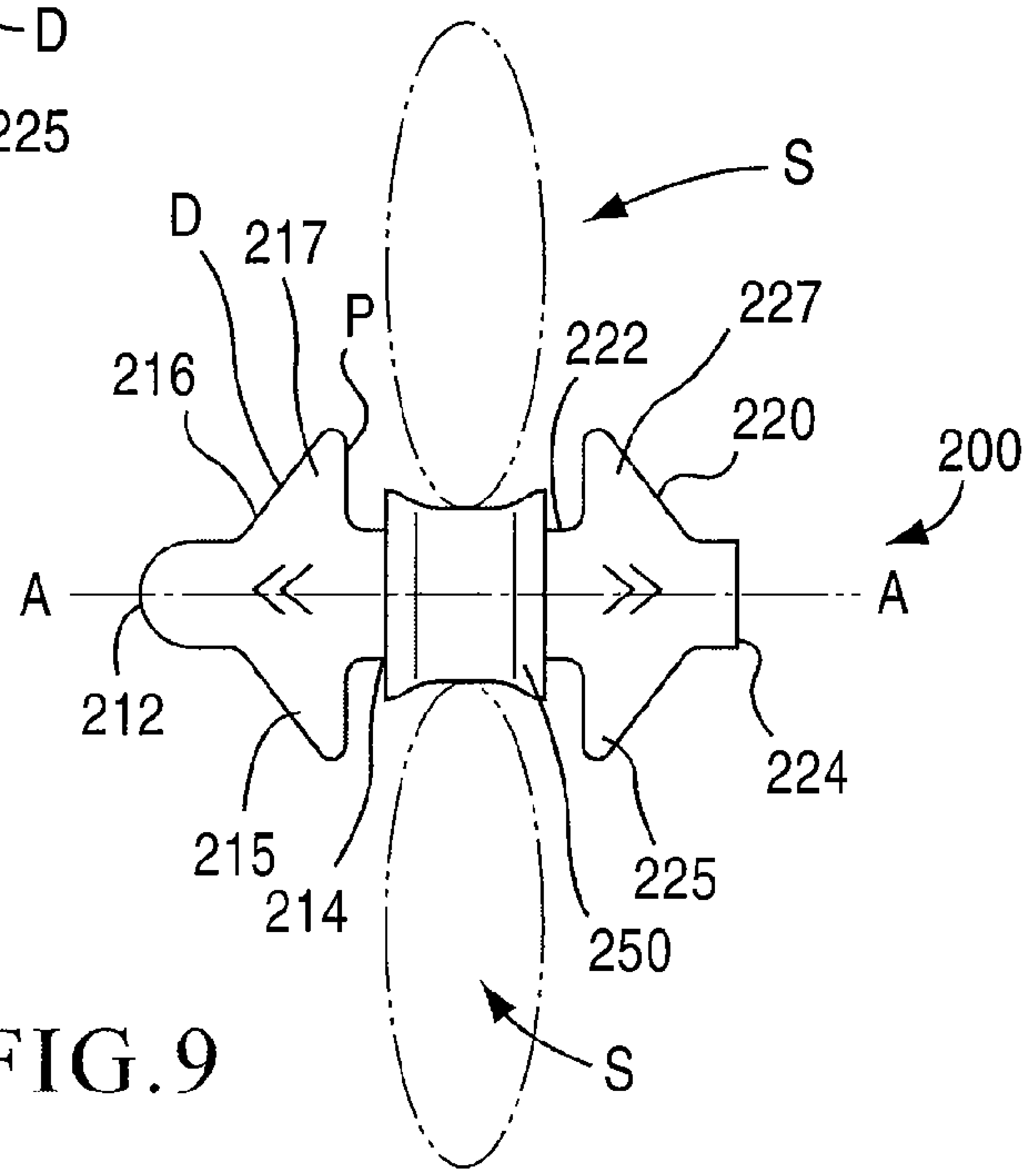


FIG.9

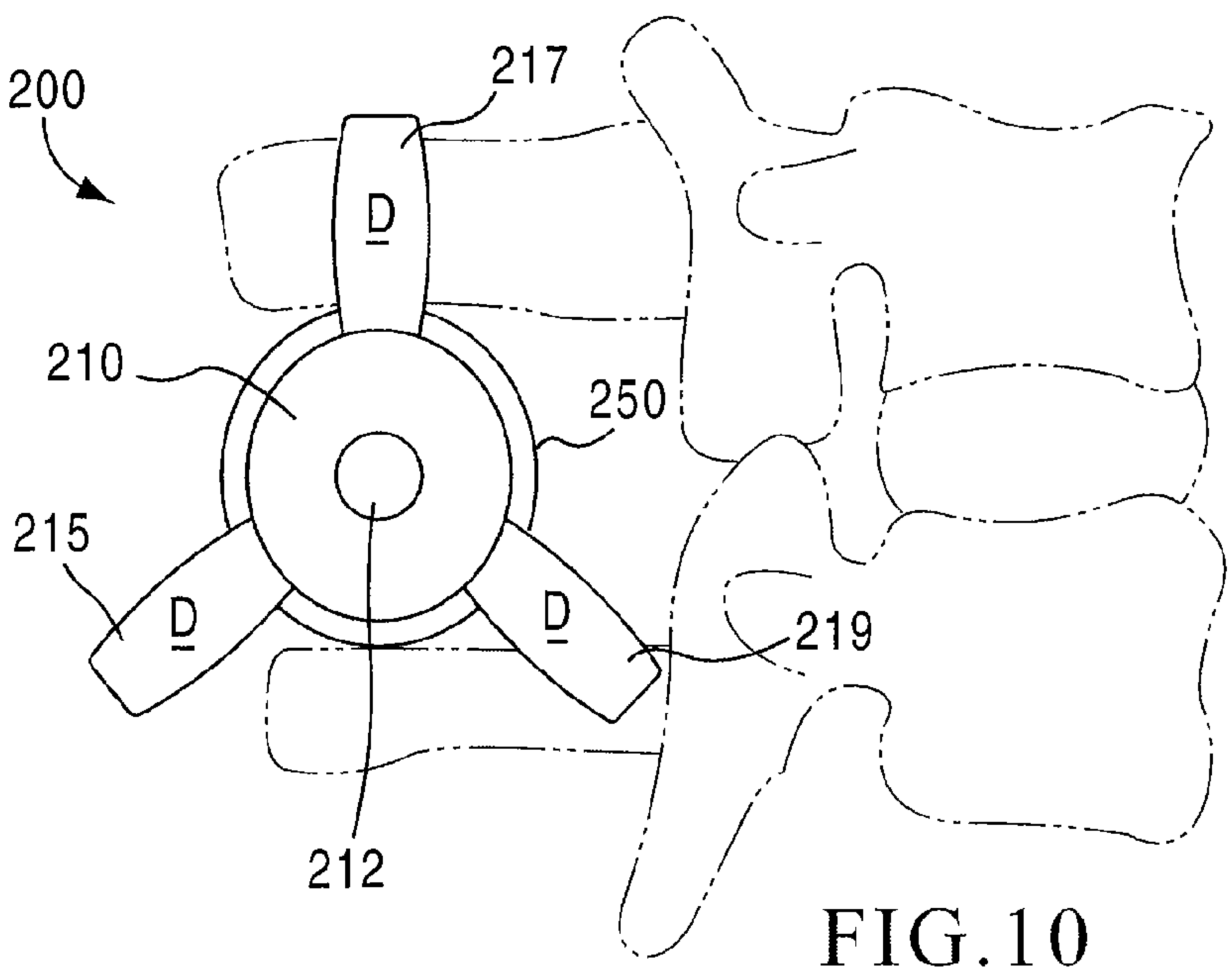
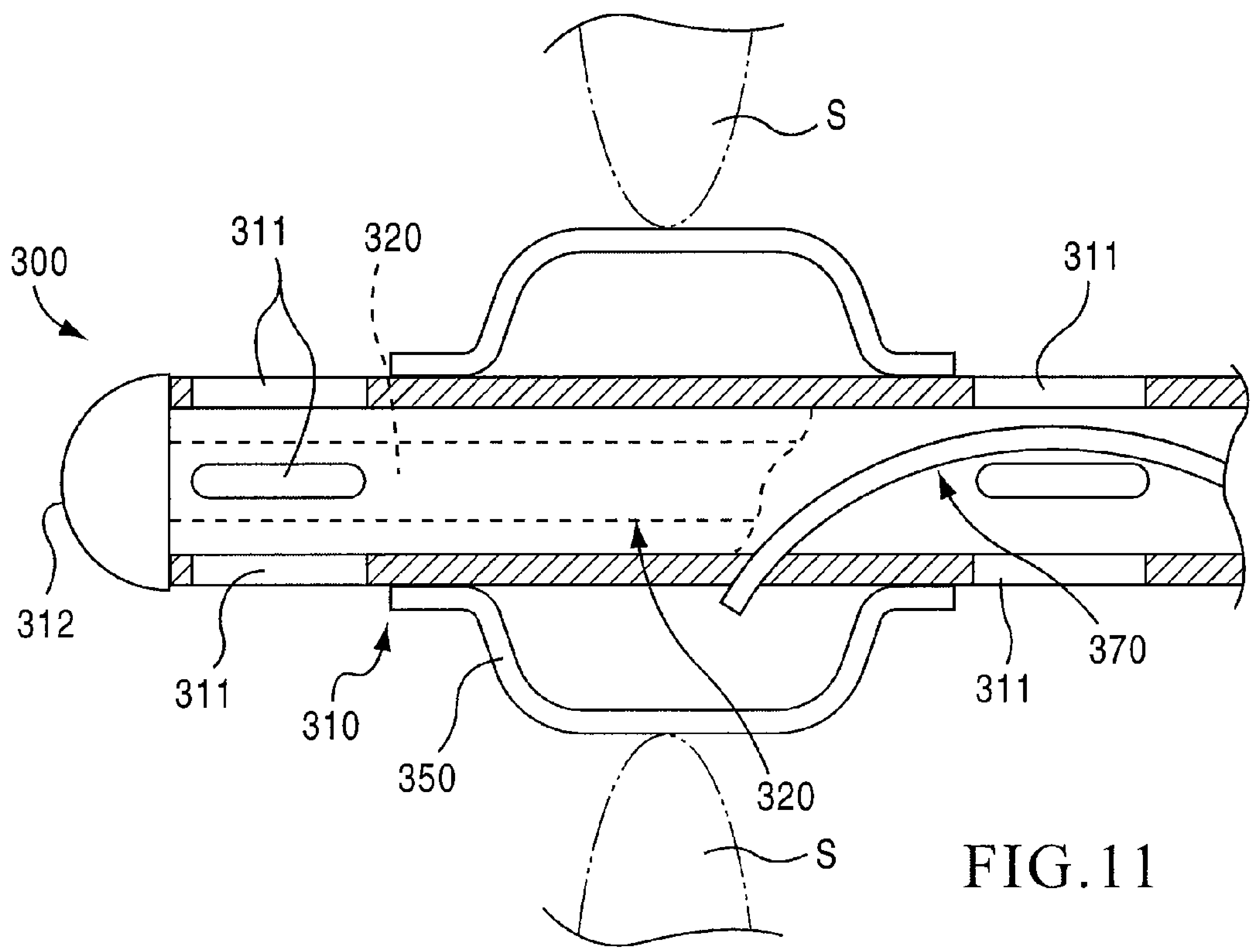


FIG.10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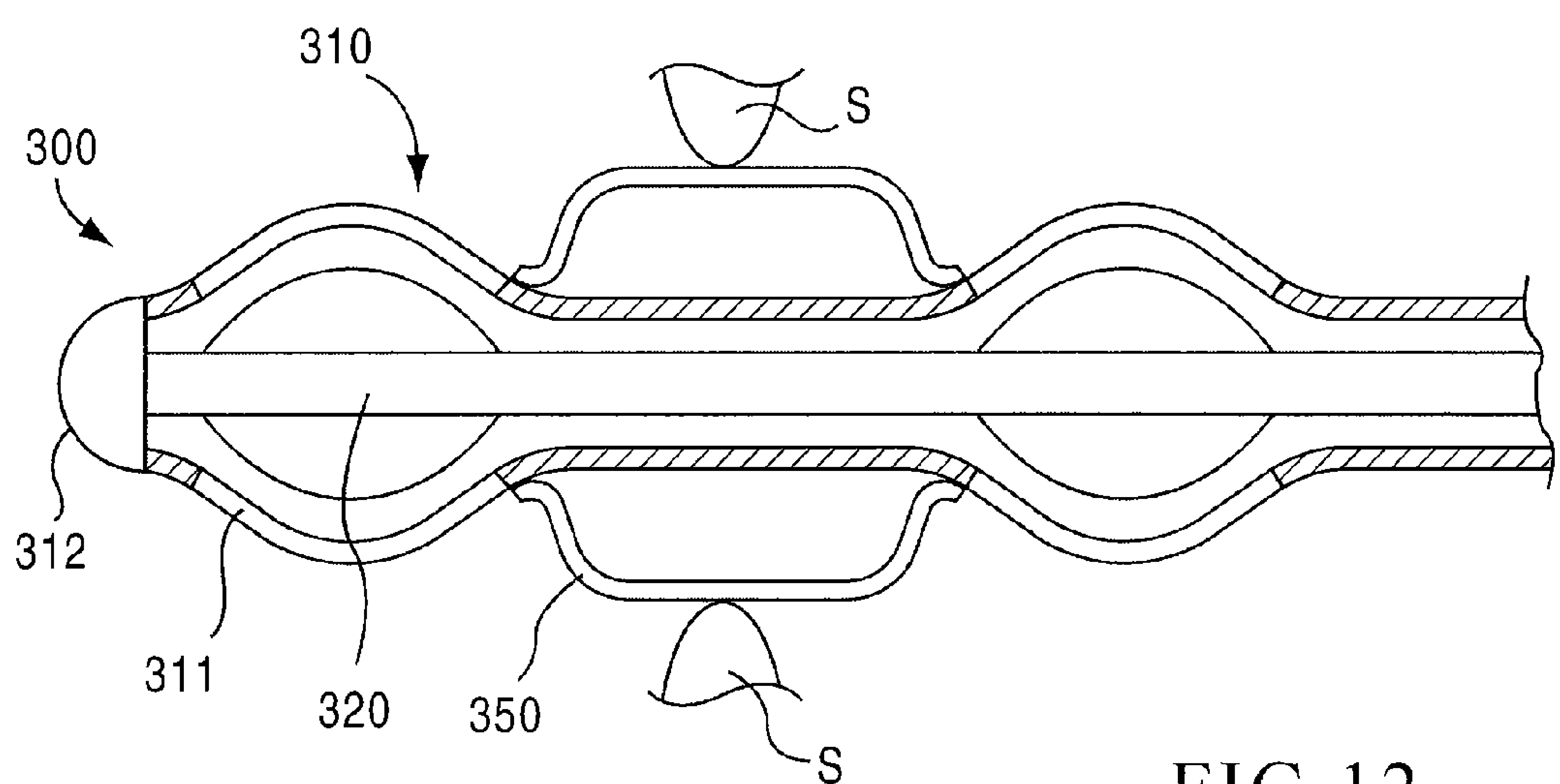
311
310
350
320
S
311
370

FIG.11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S
300
312
311
320
350
S

FIG.12

FIG. 13

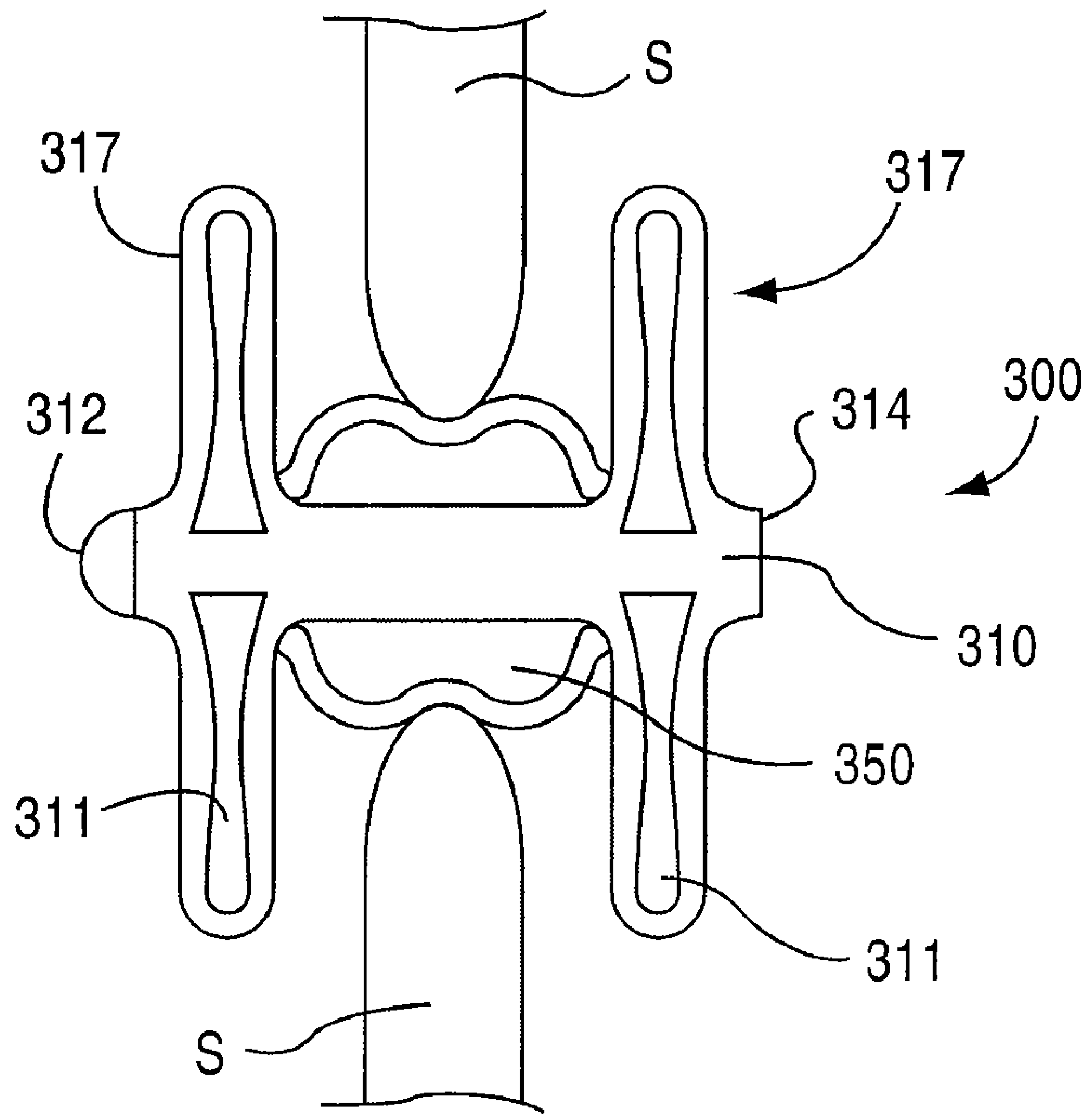
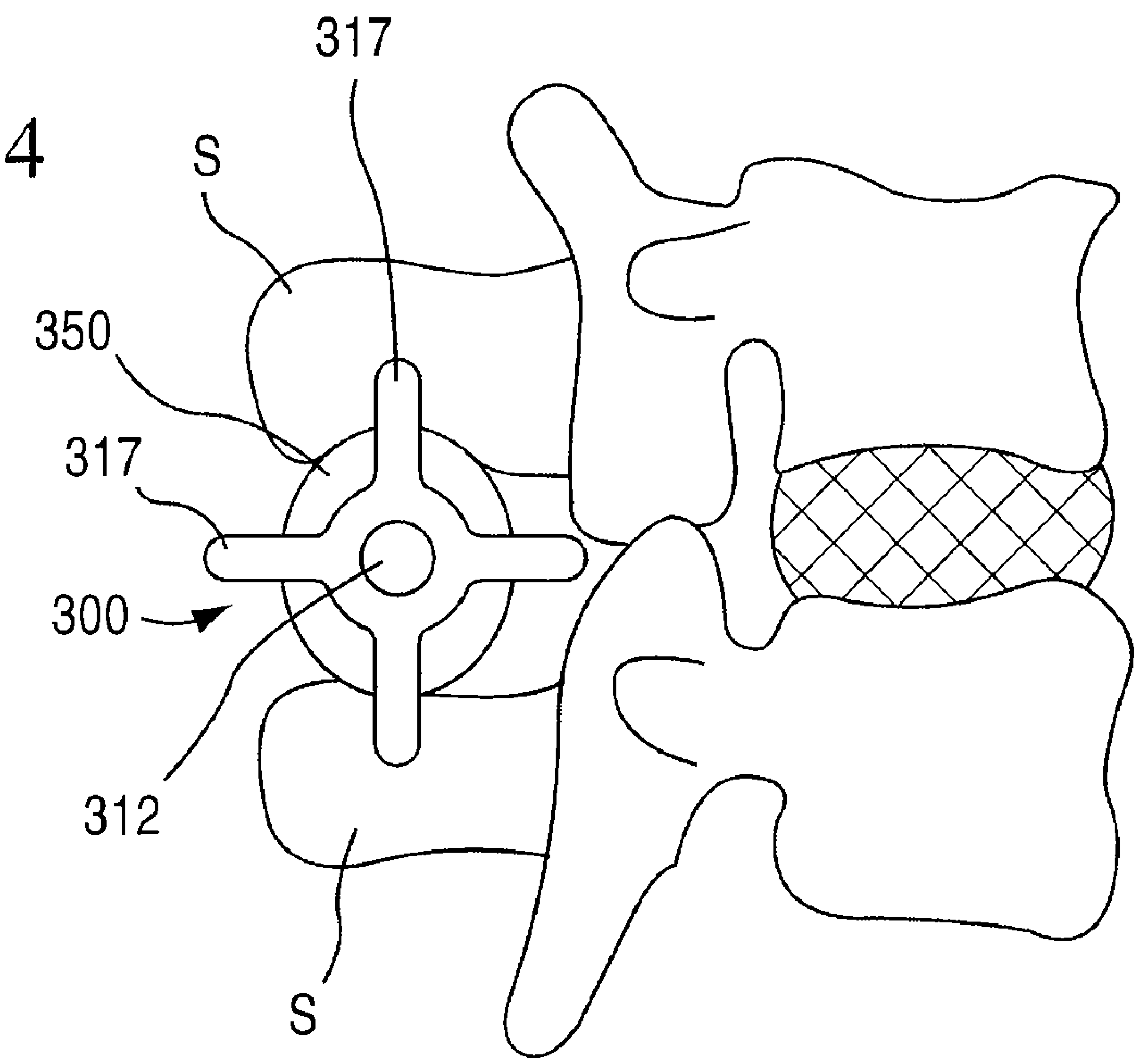
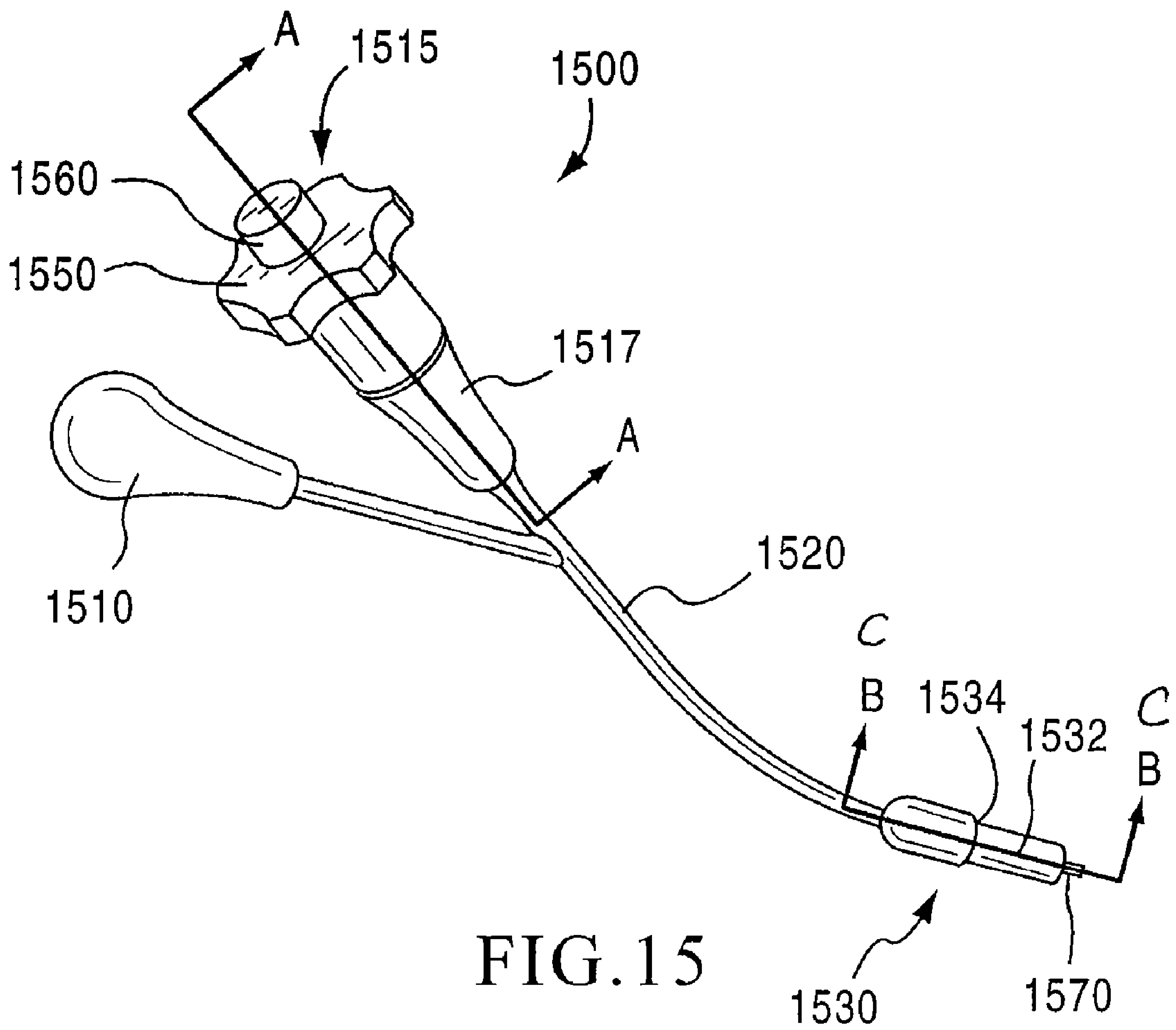


FIG. 14

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1520
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1532
C
B
1530
1570

FIG.15

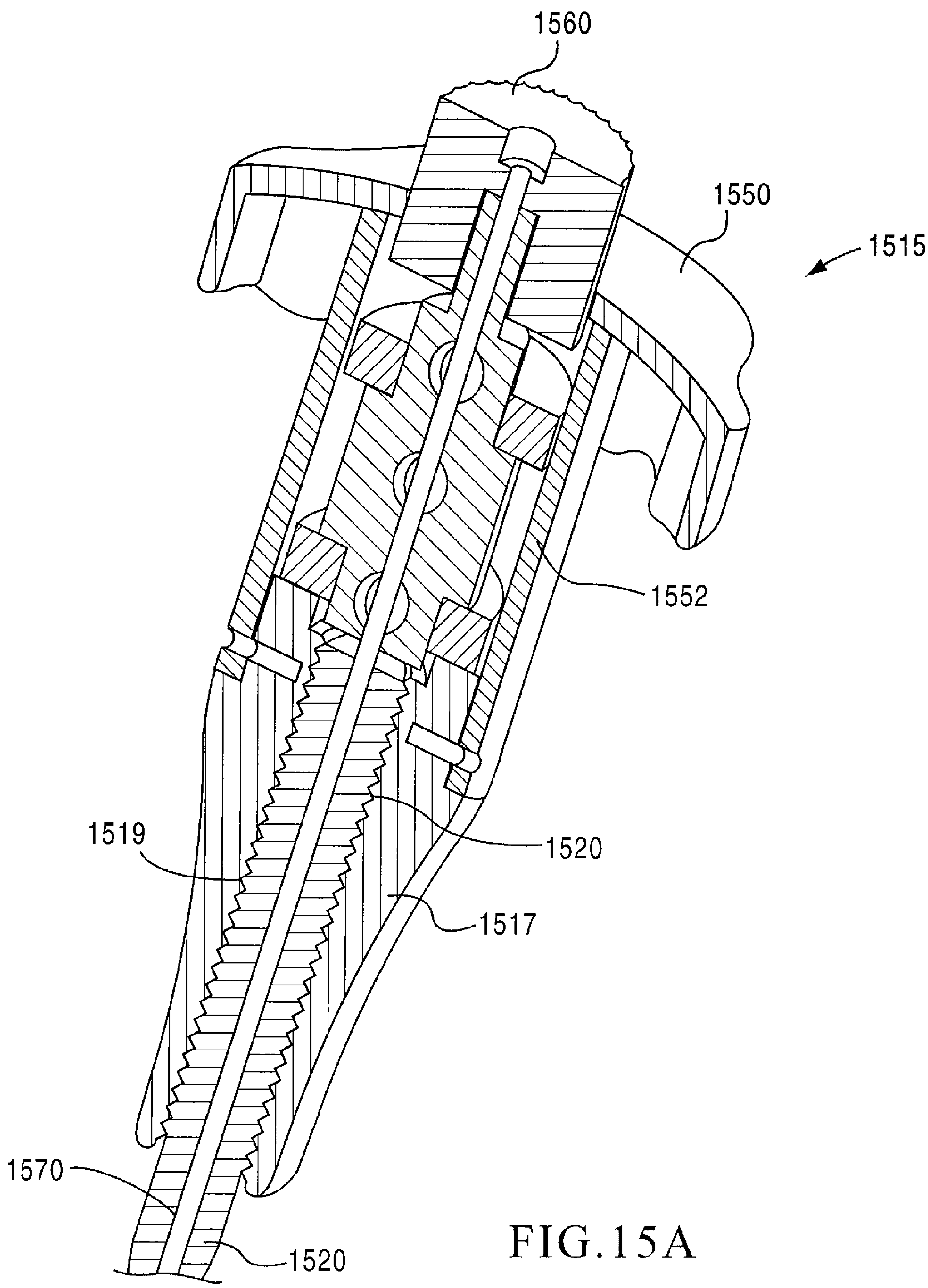


FIG.15A

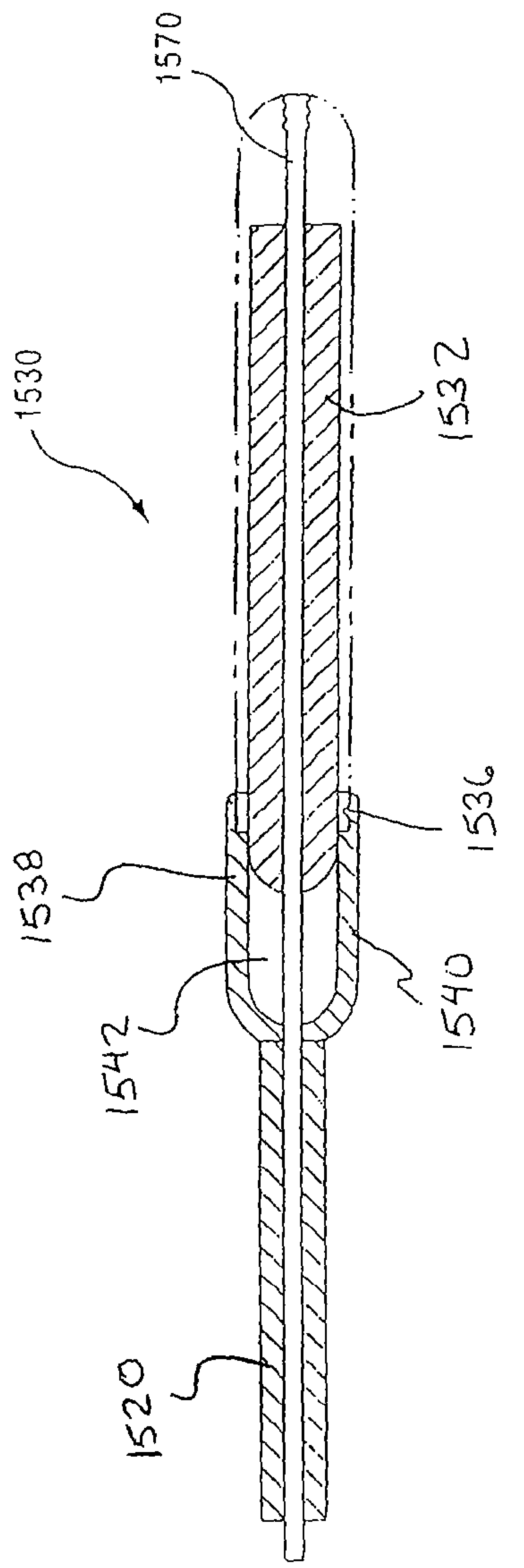


FIG. 15B

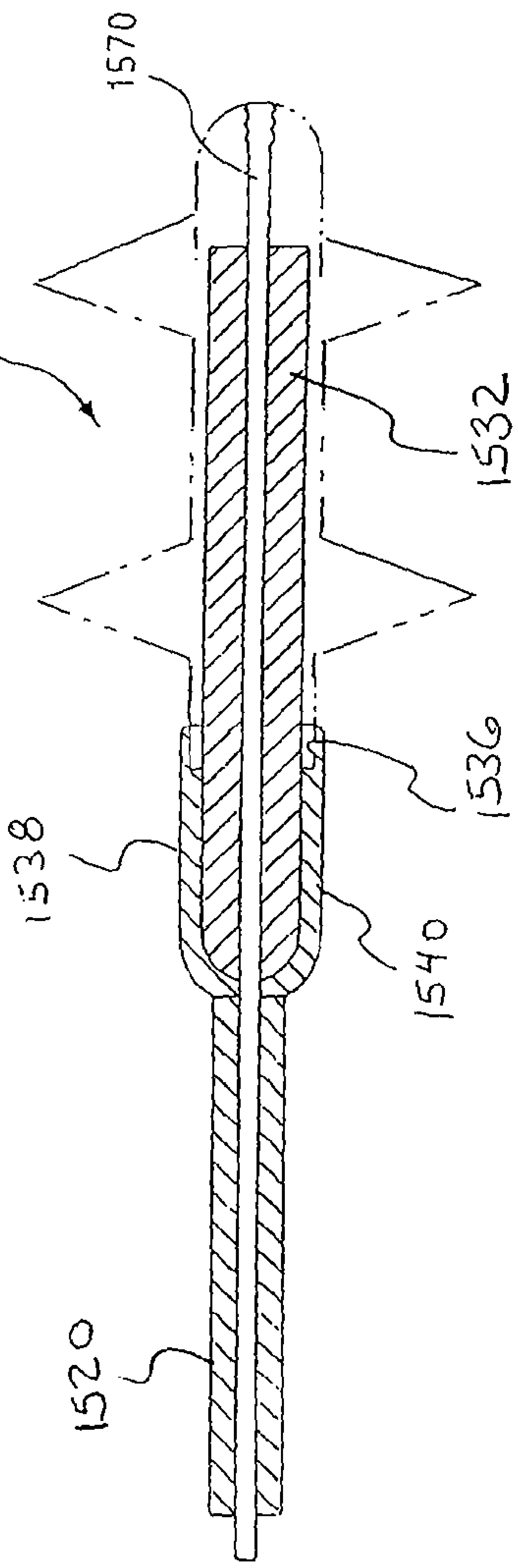


FIG. 15C

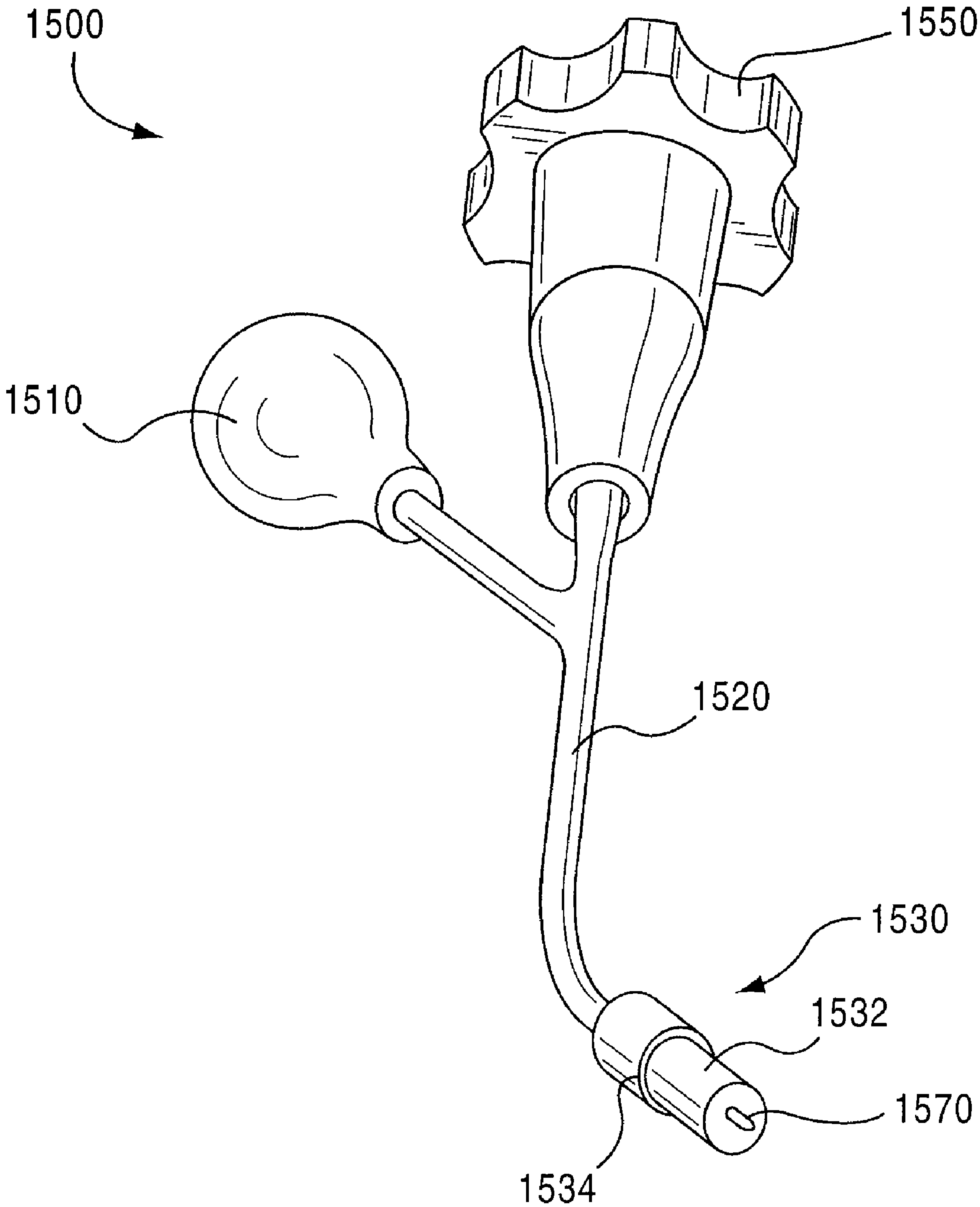


FIG.16

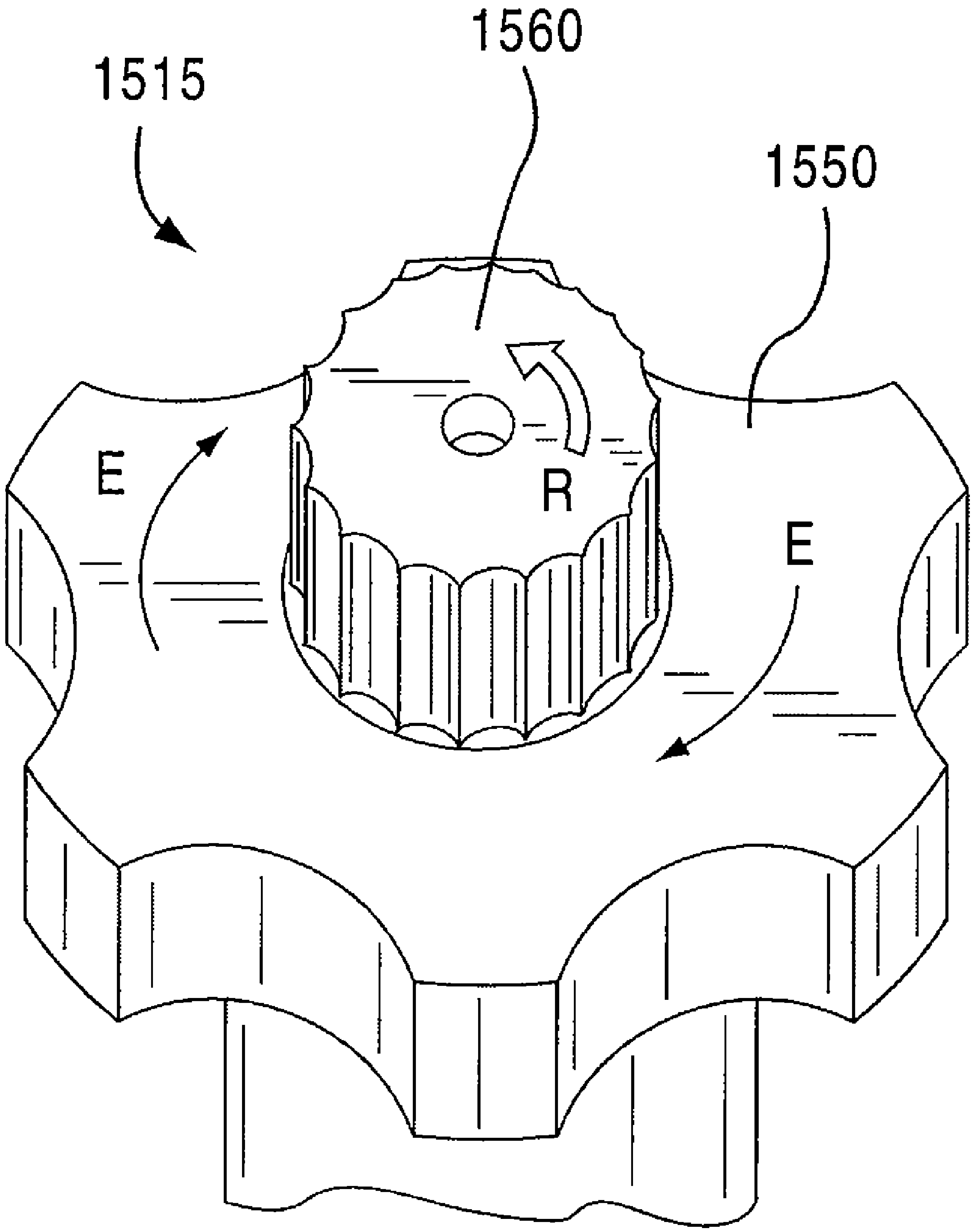


FIG.17

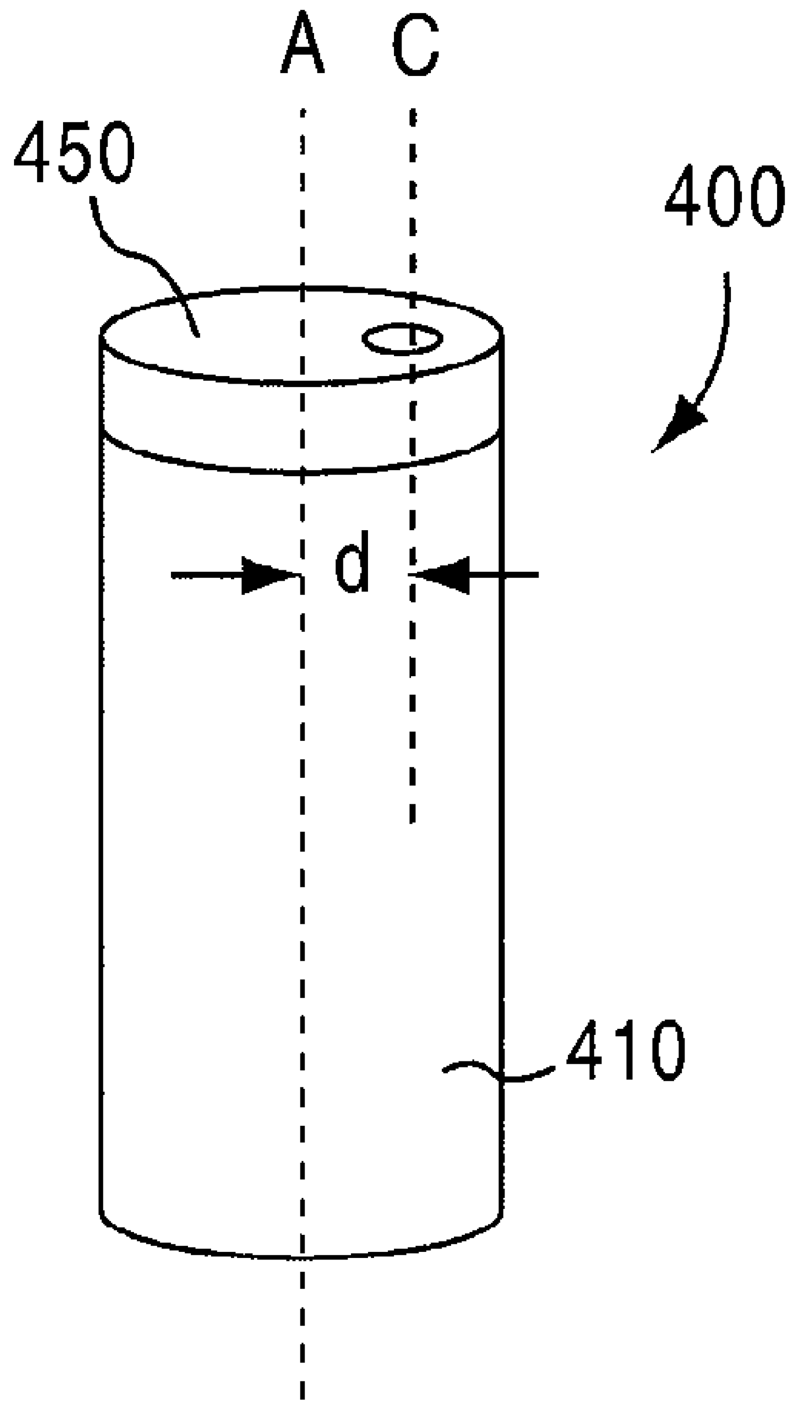


FIG.18

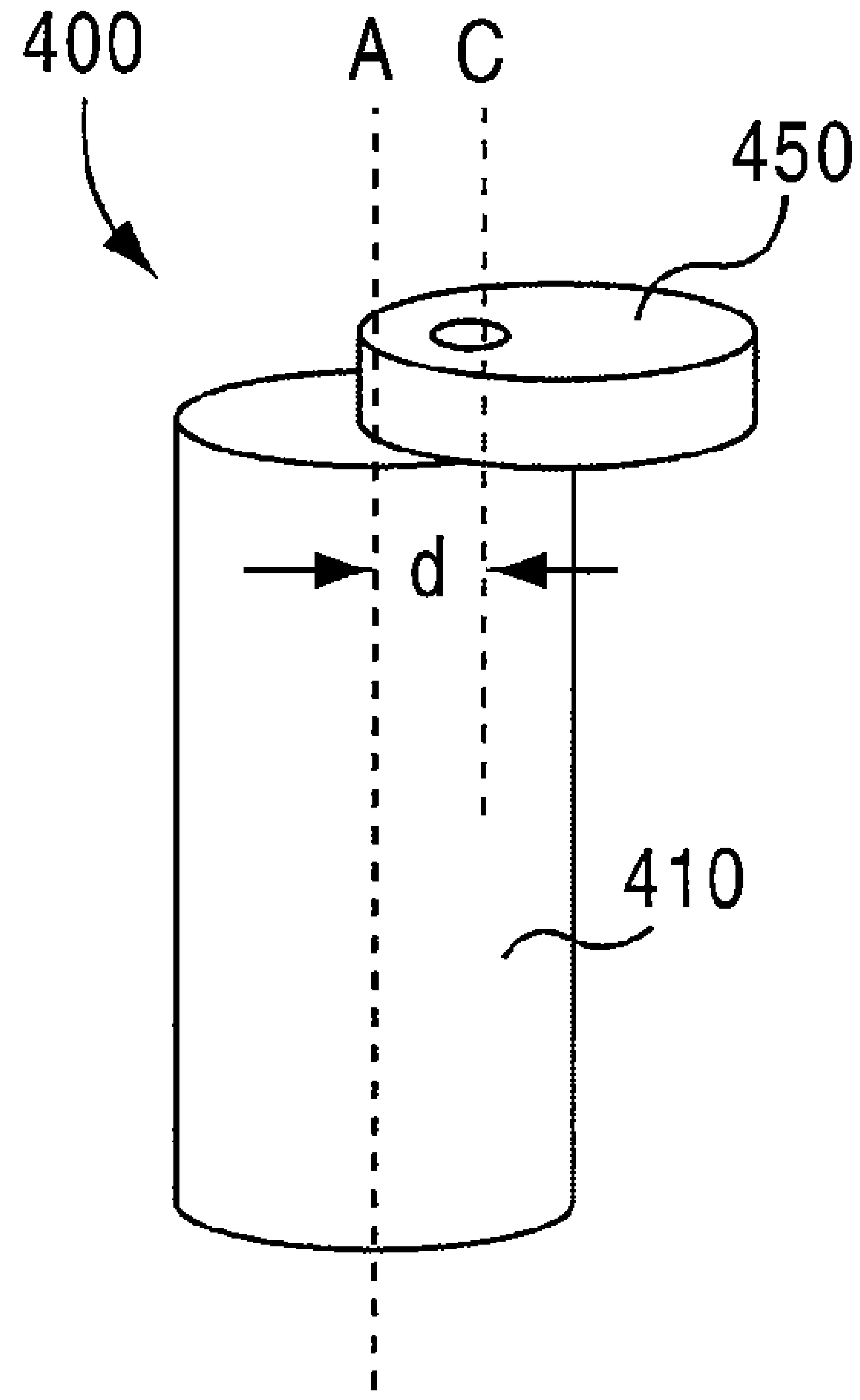


FIG.19

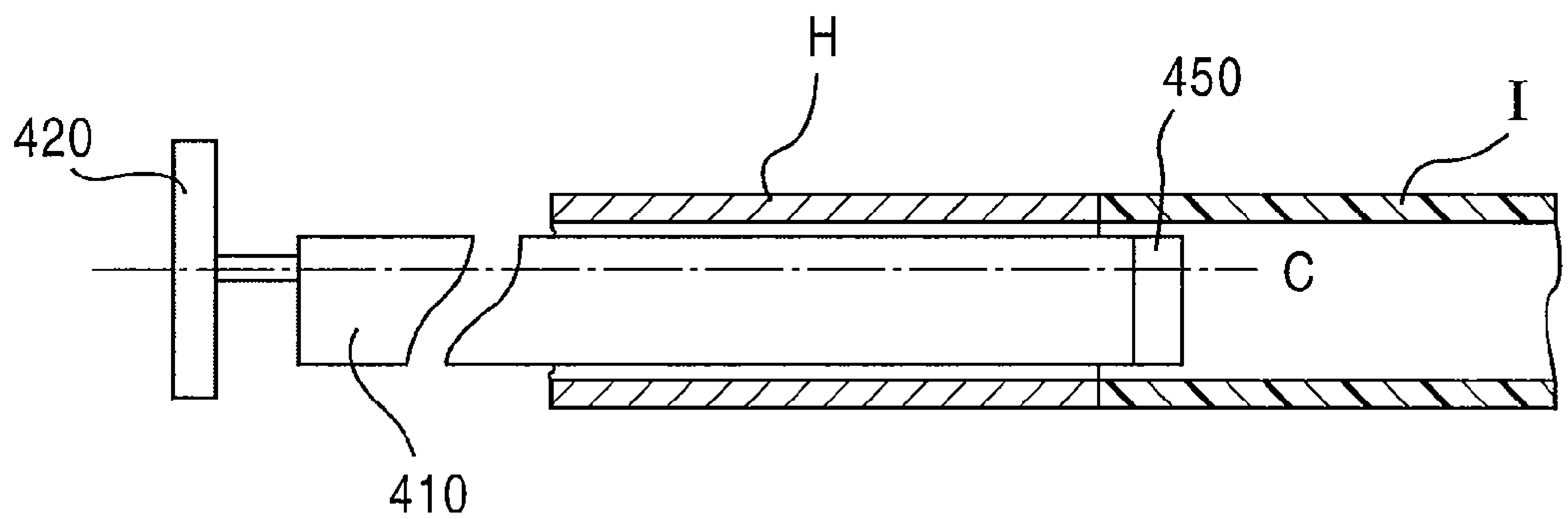


FIG.20

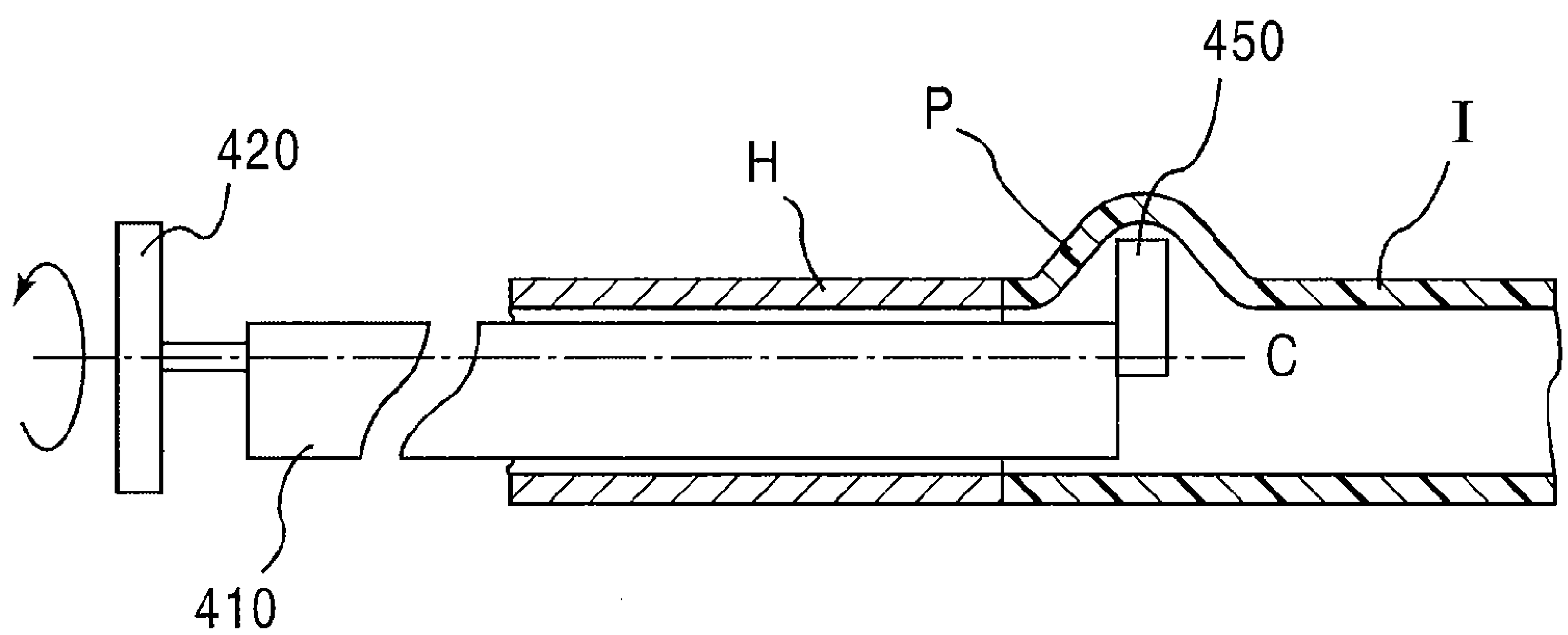


FIG.21

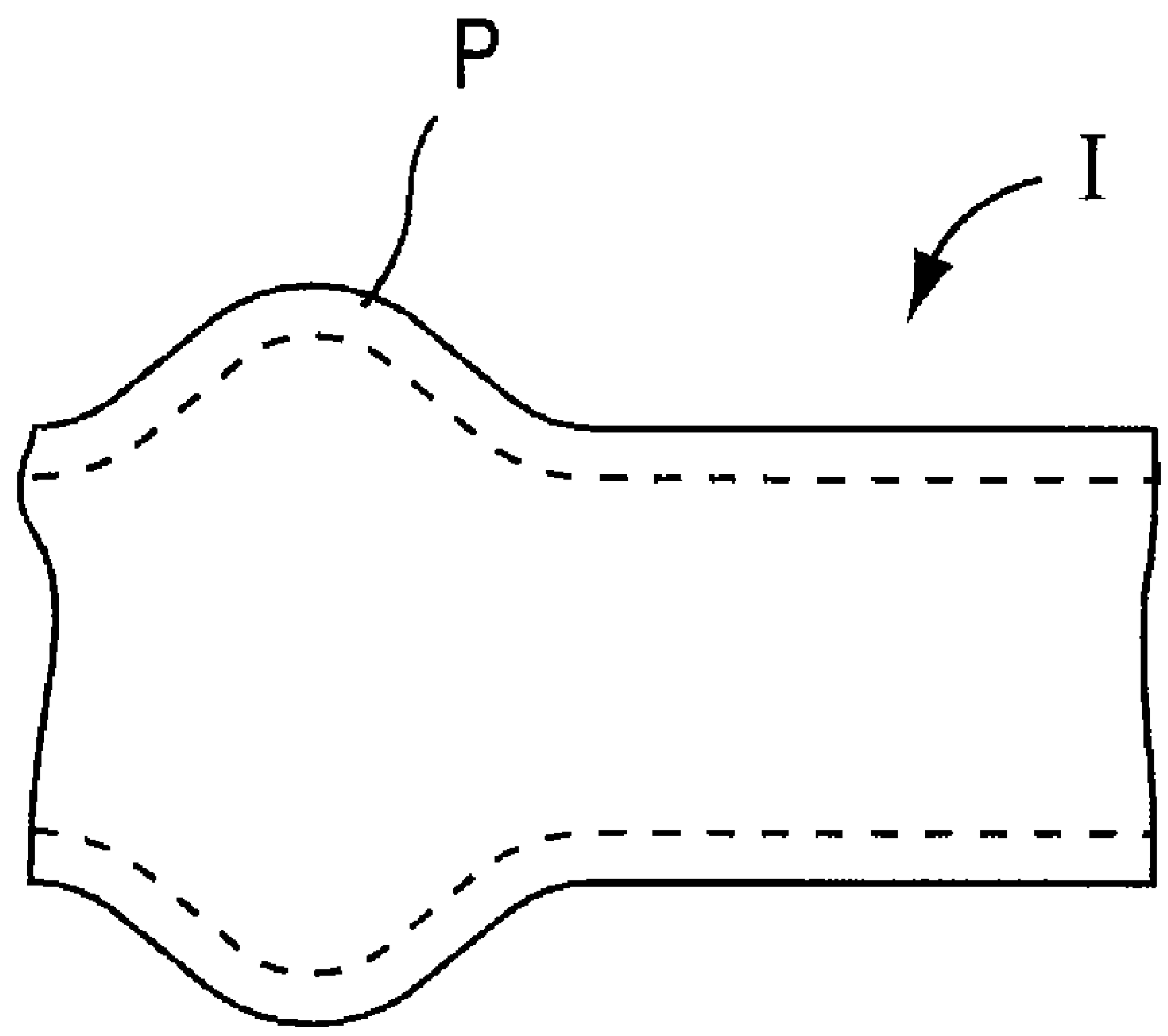


FIG.22

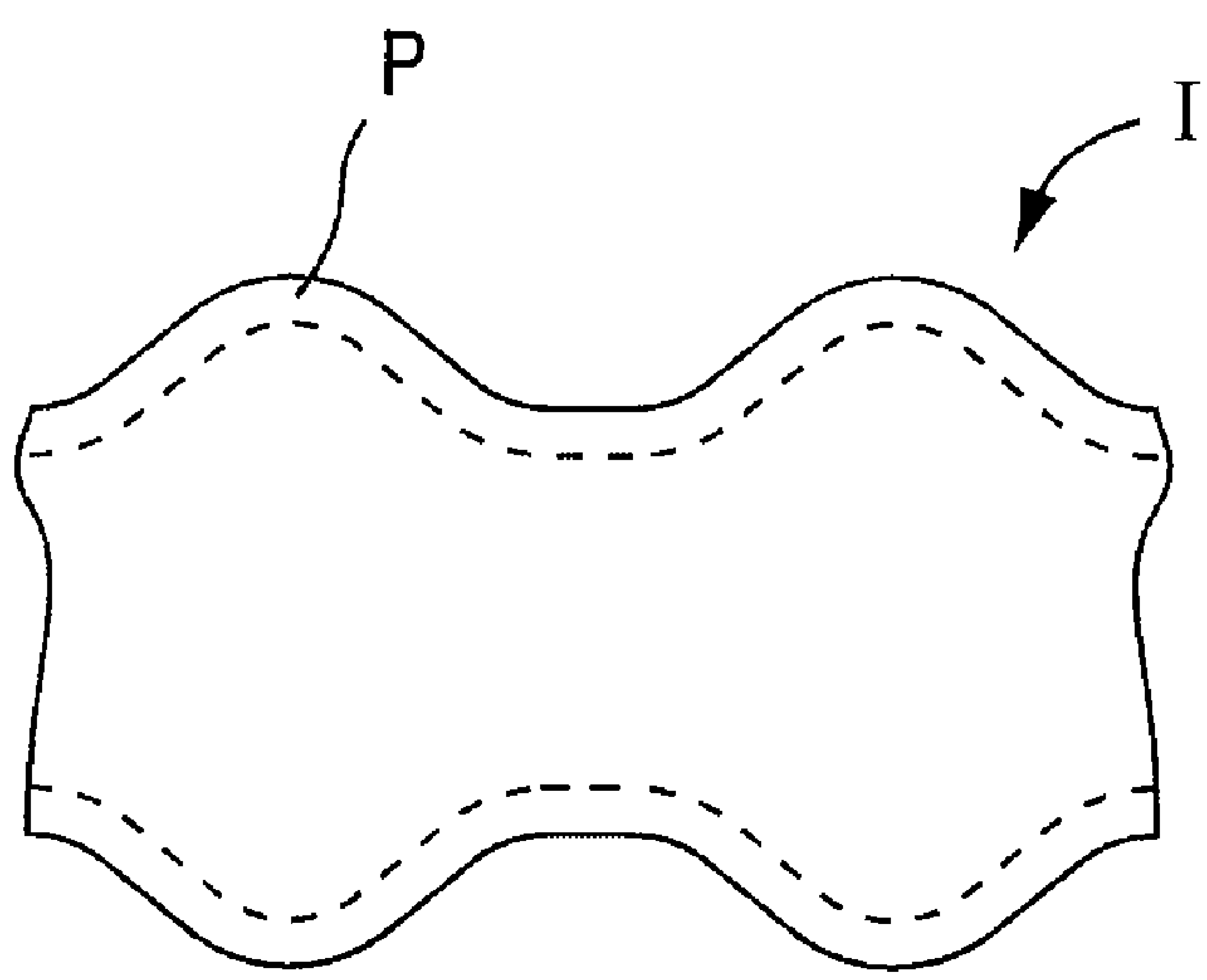


FIG.23

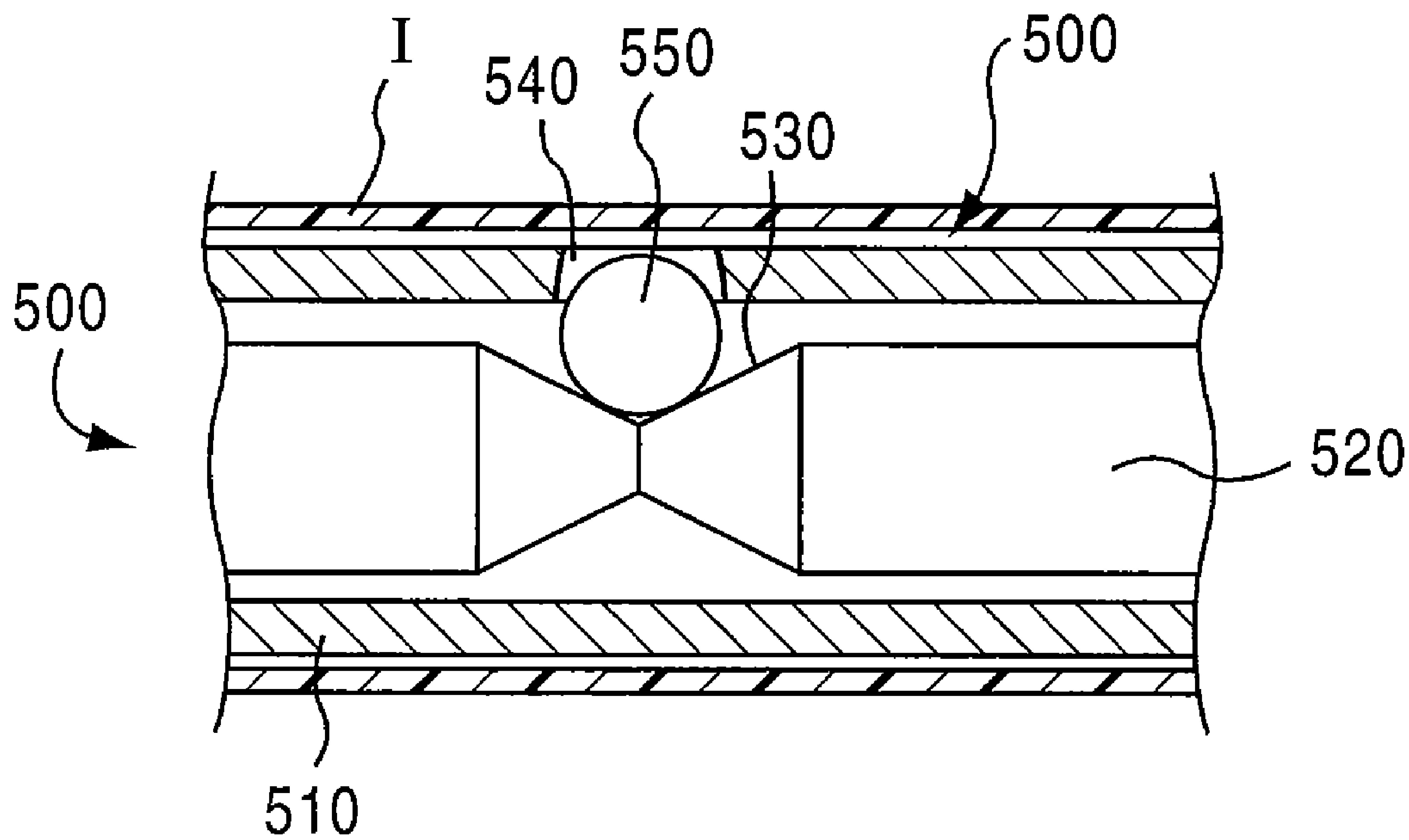


FIG.24

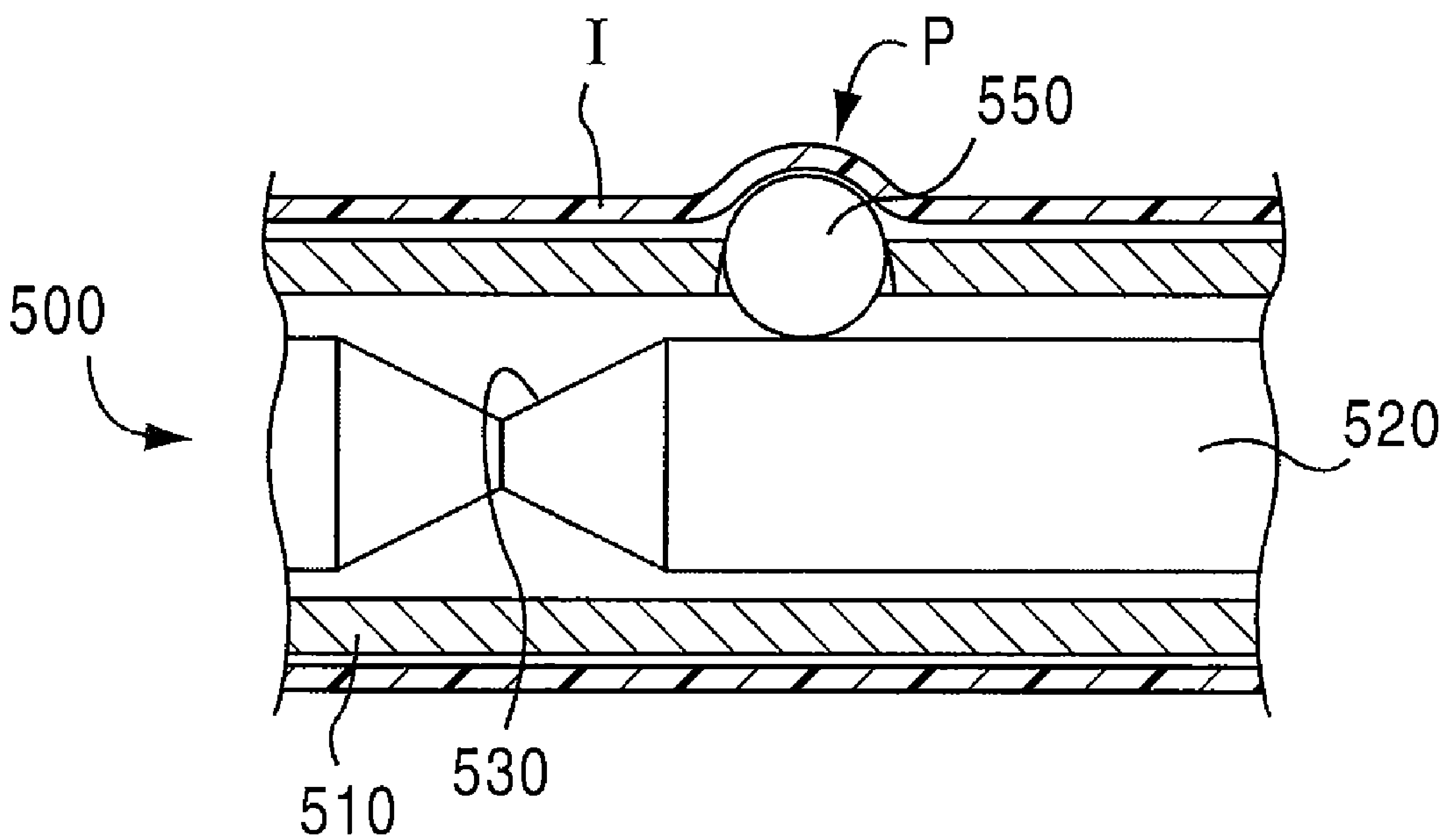


FIG.25

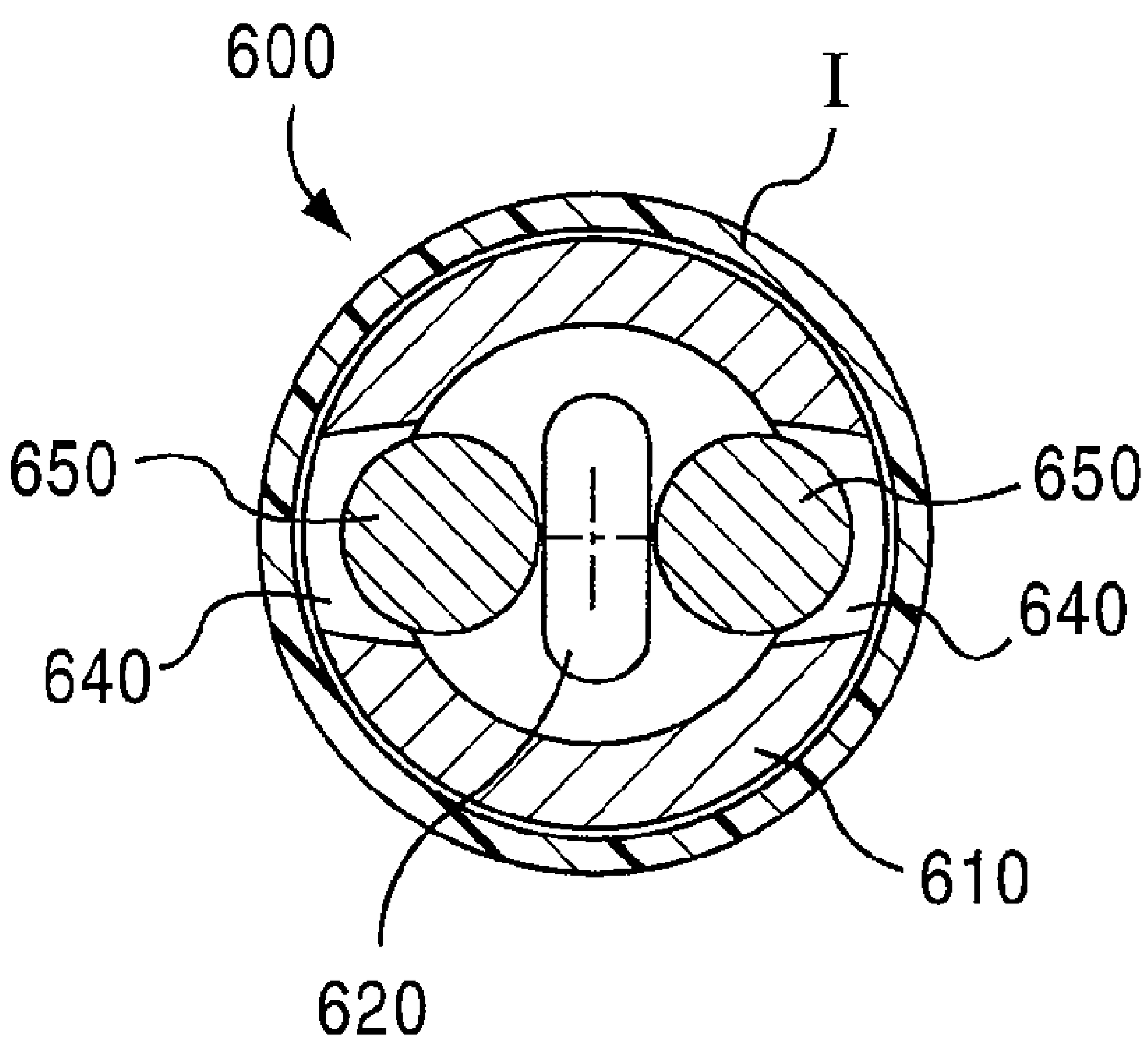


FIG.26

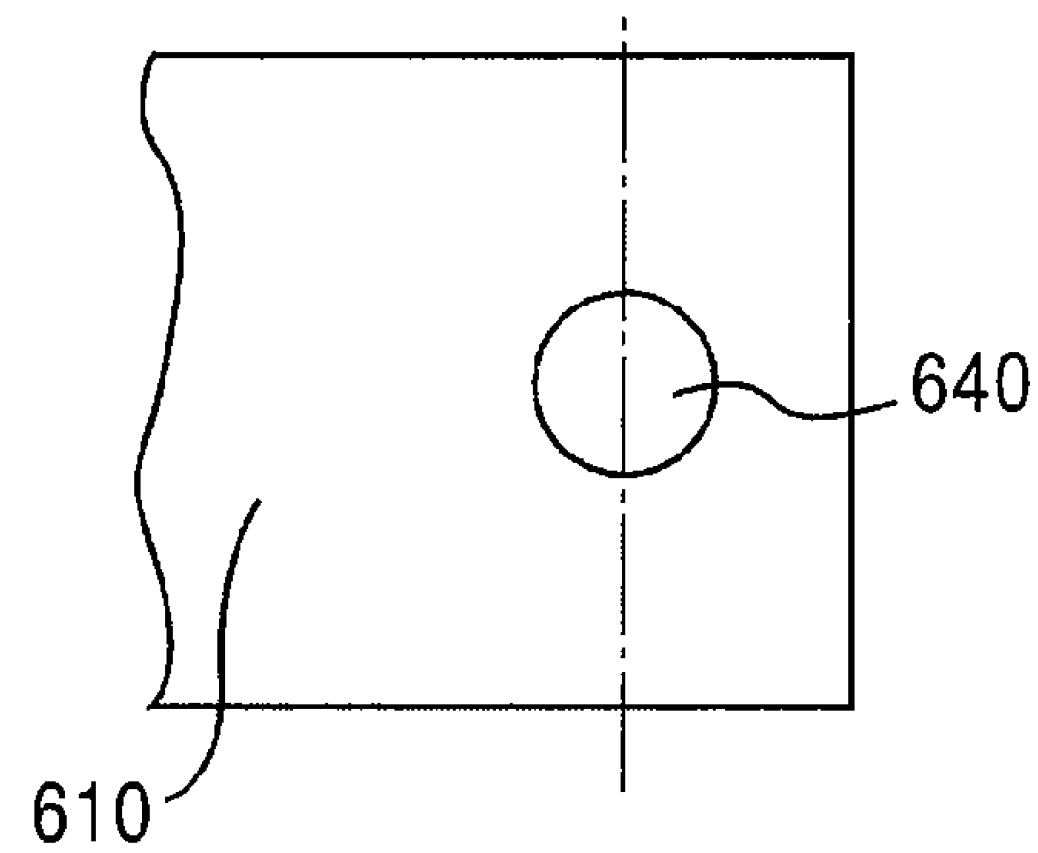


FIG.27

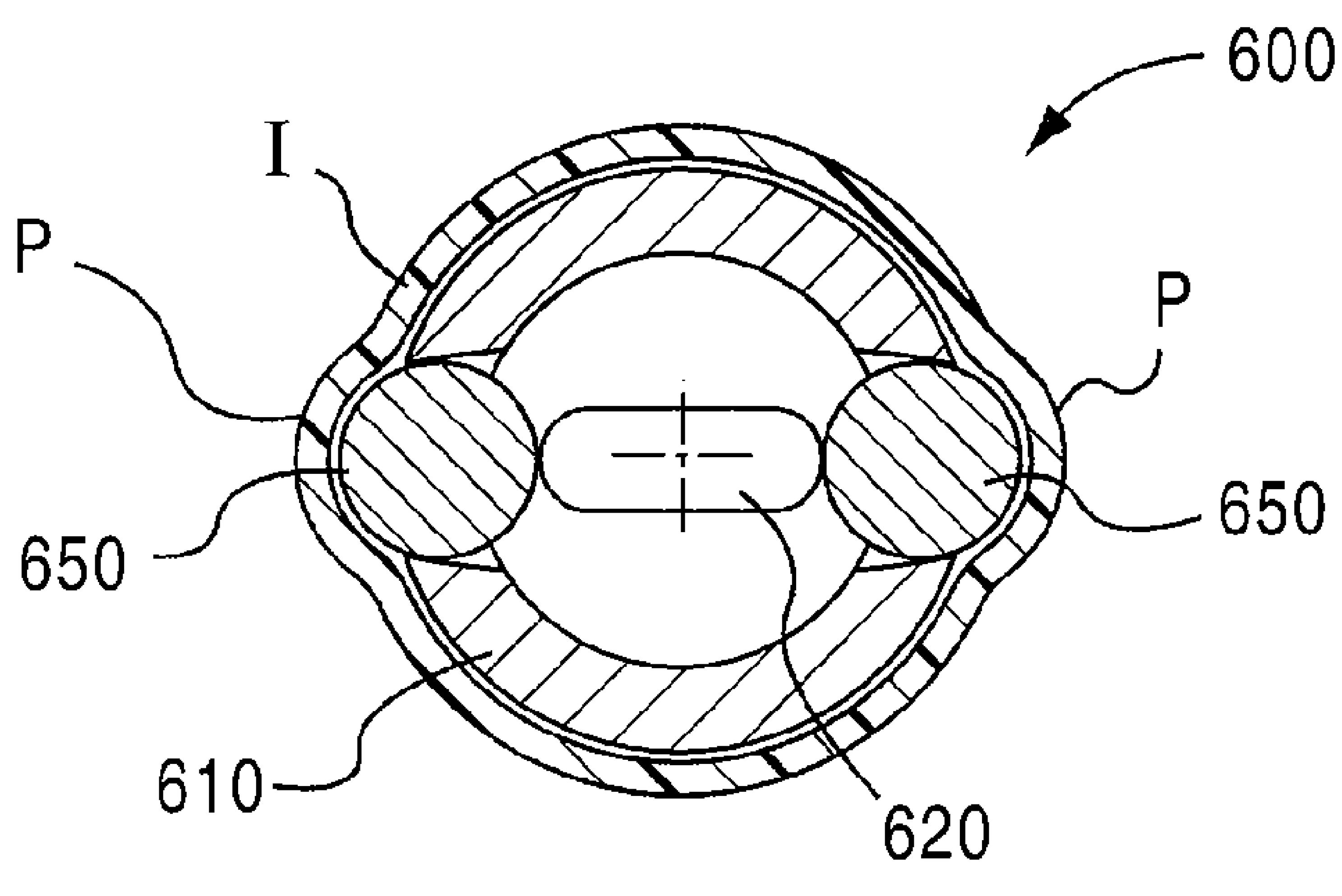


FIG.28

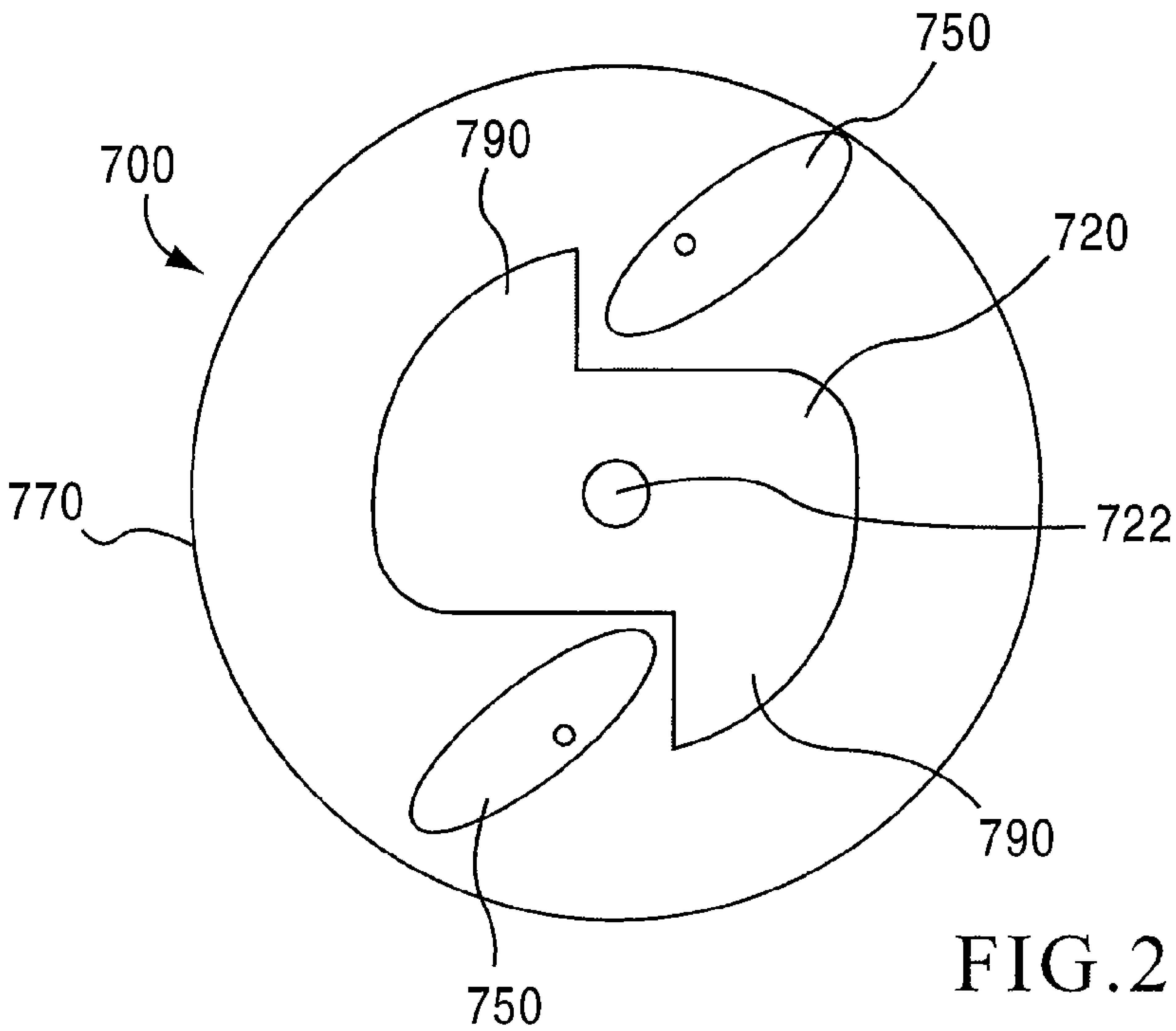


FIG.29

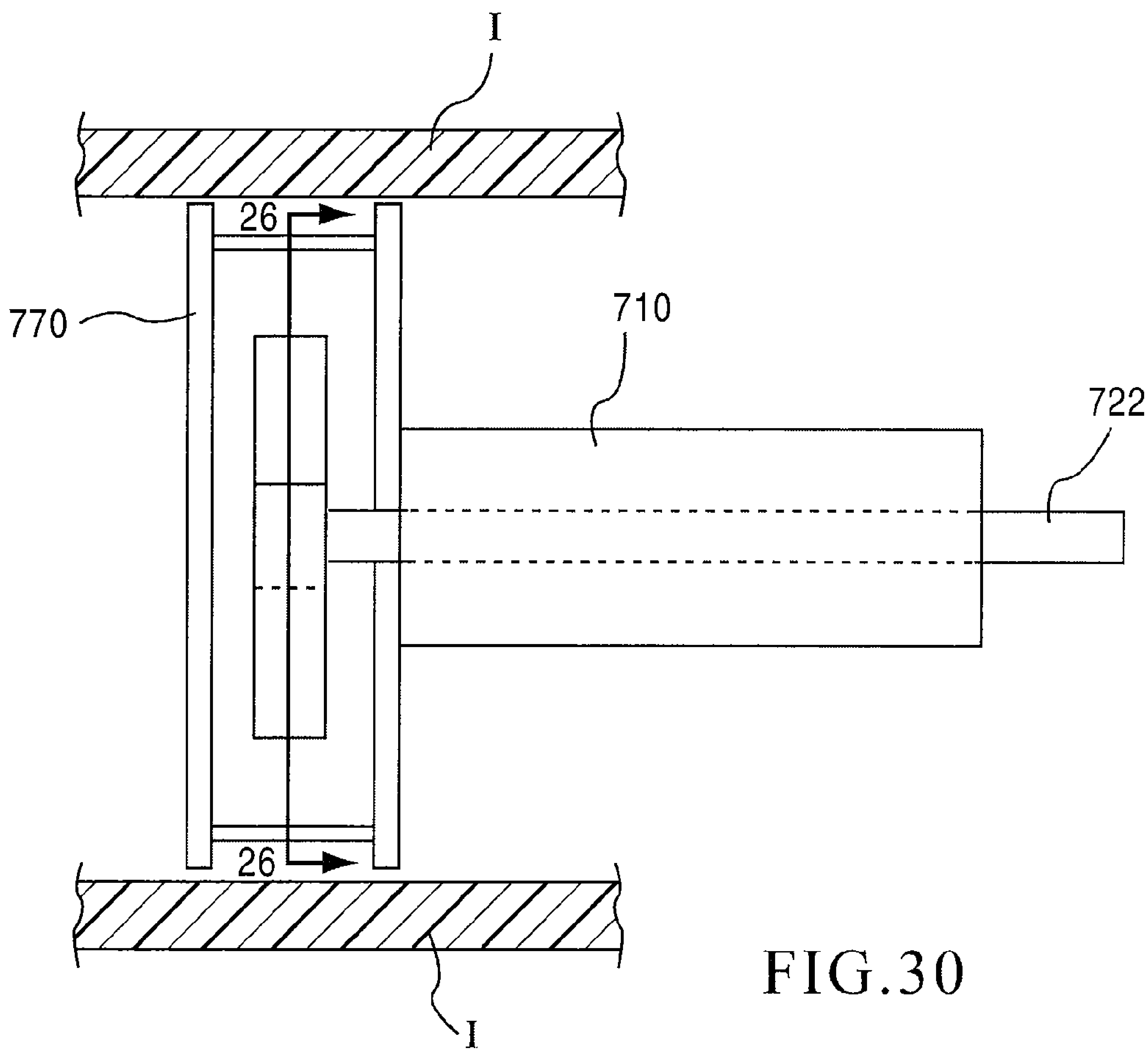


FIG.30

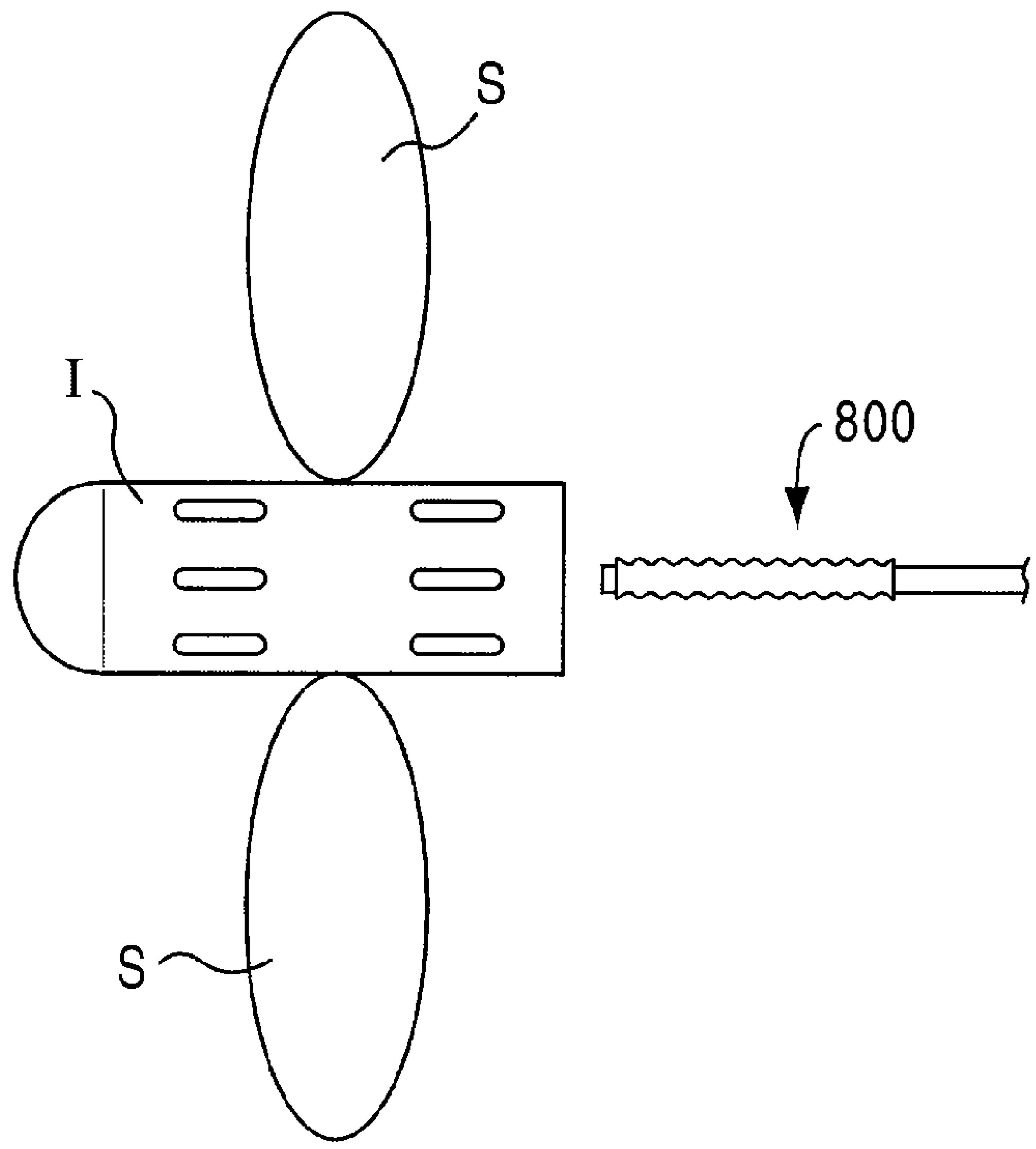


FIG.31

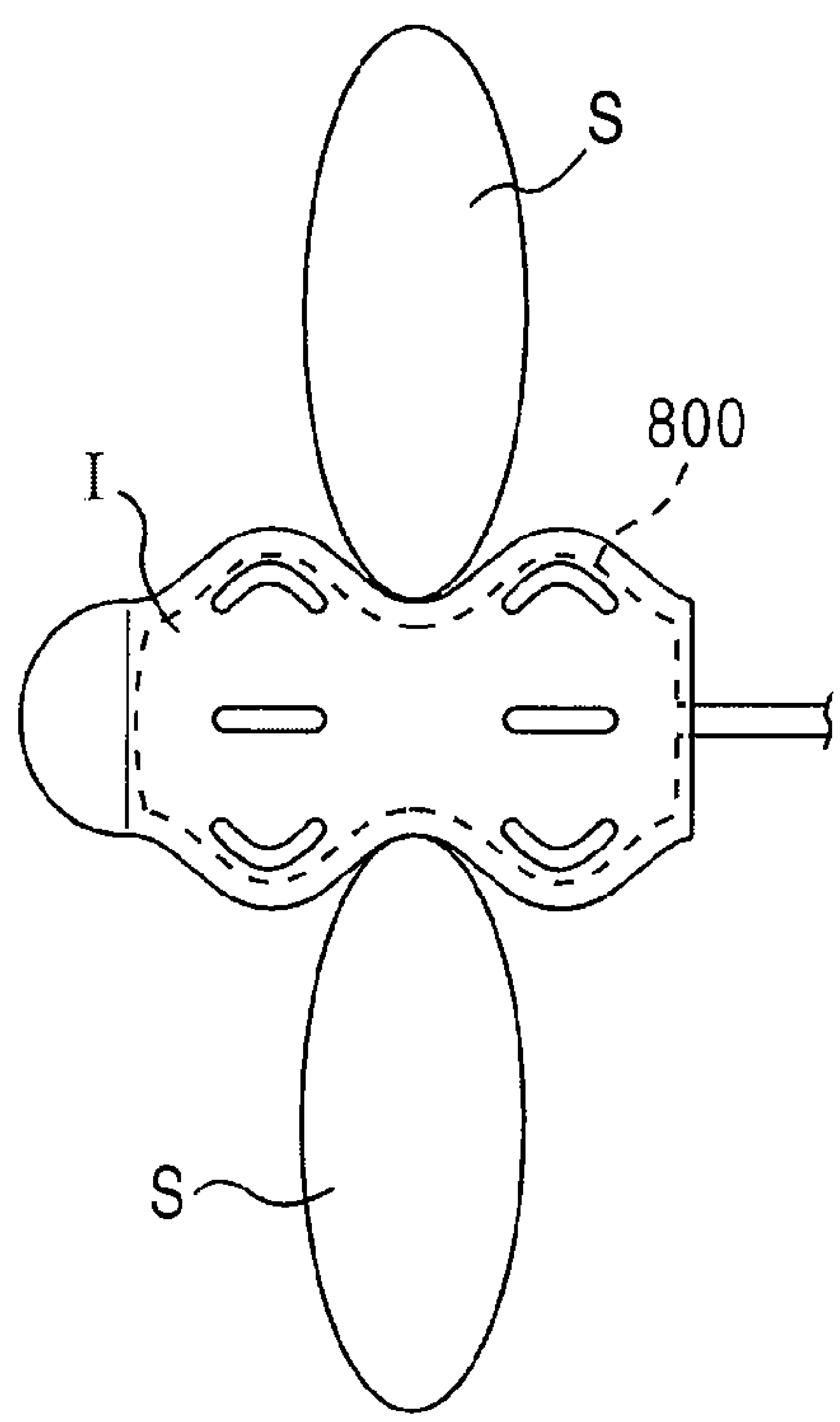


FIG.32

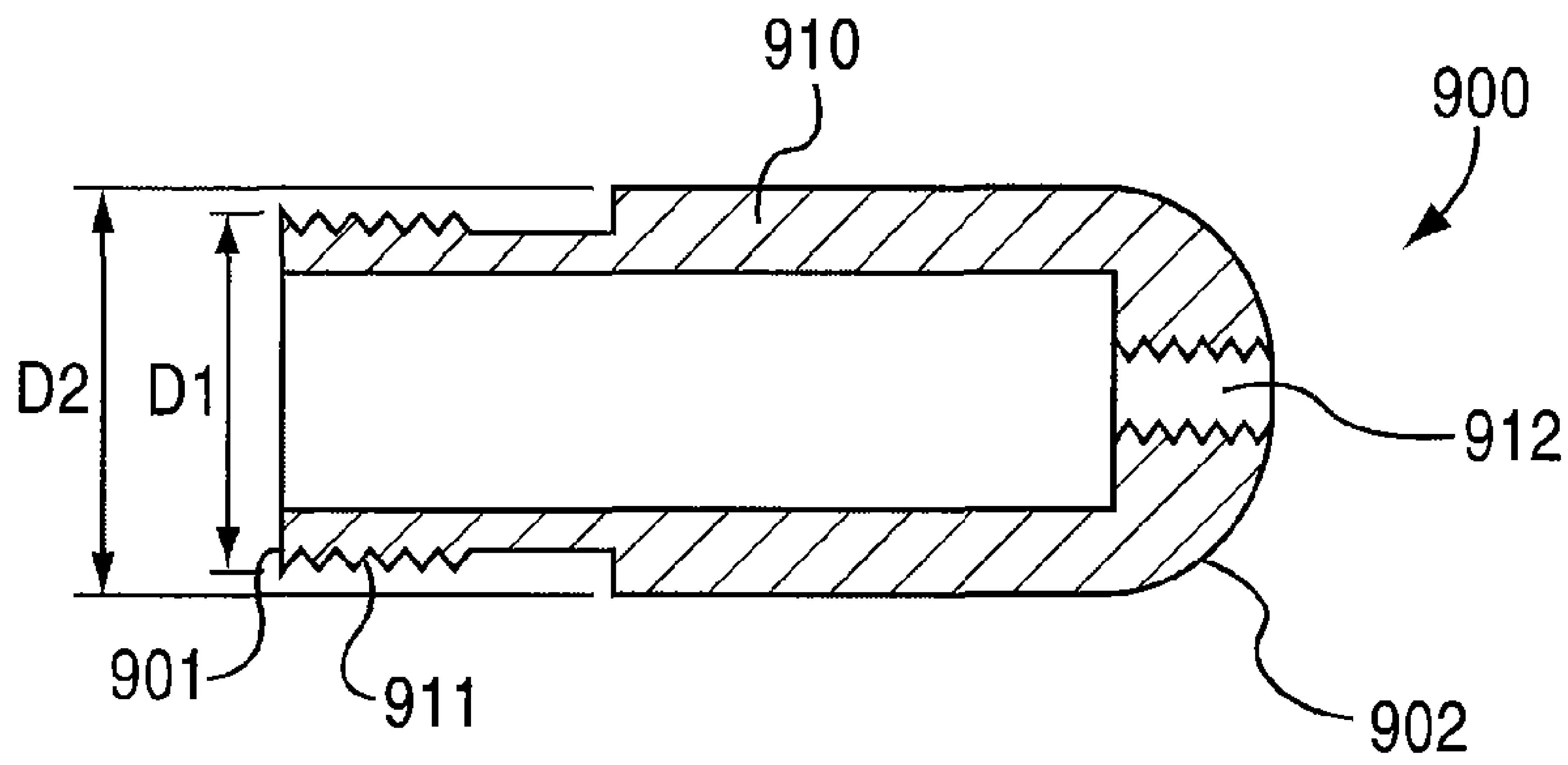


FIG.33

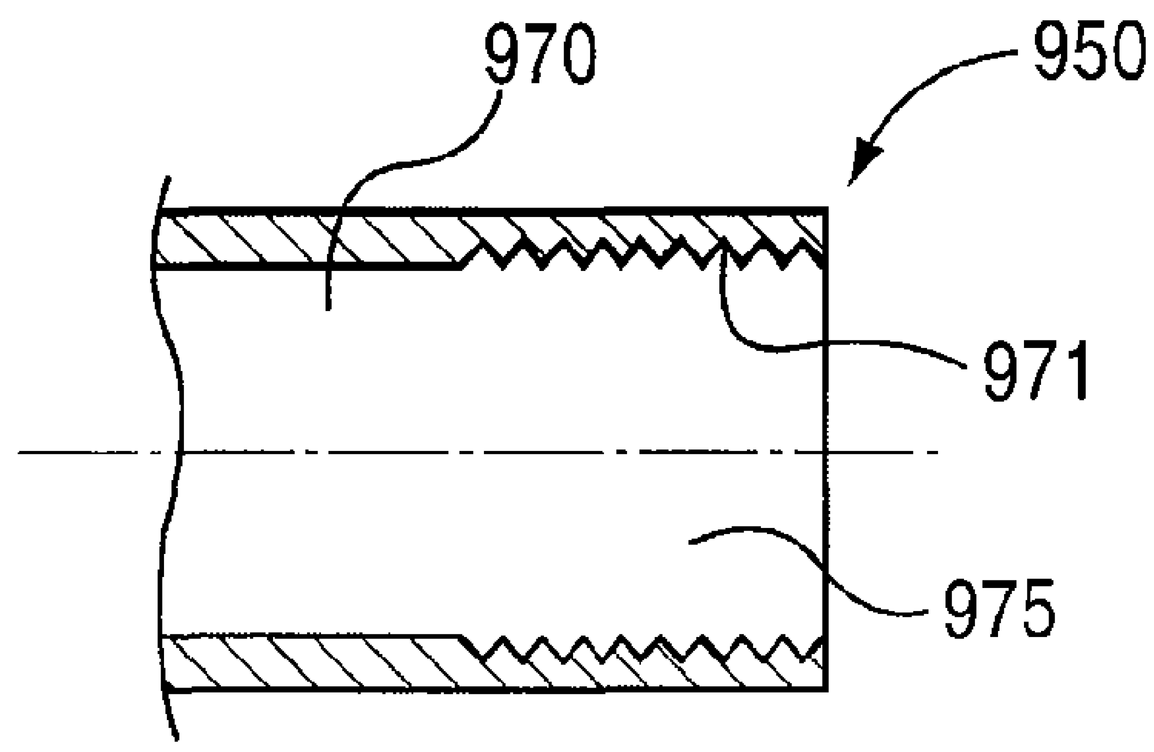


FIG.34

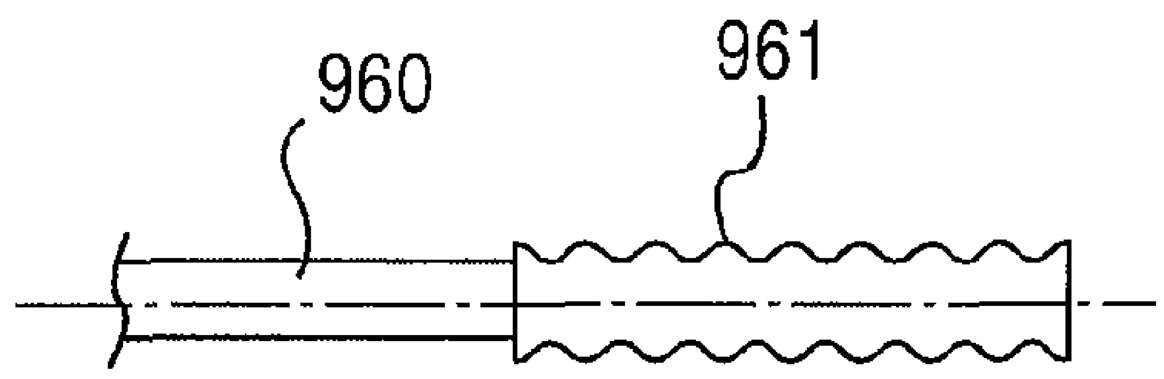


FIG.35

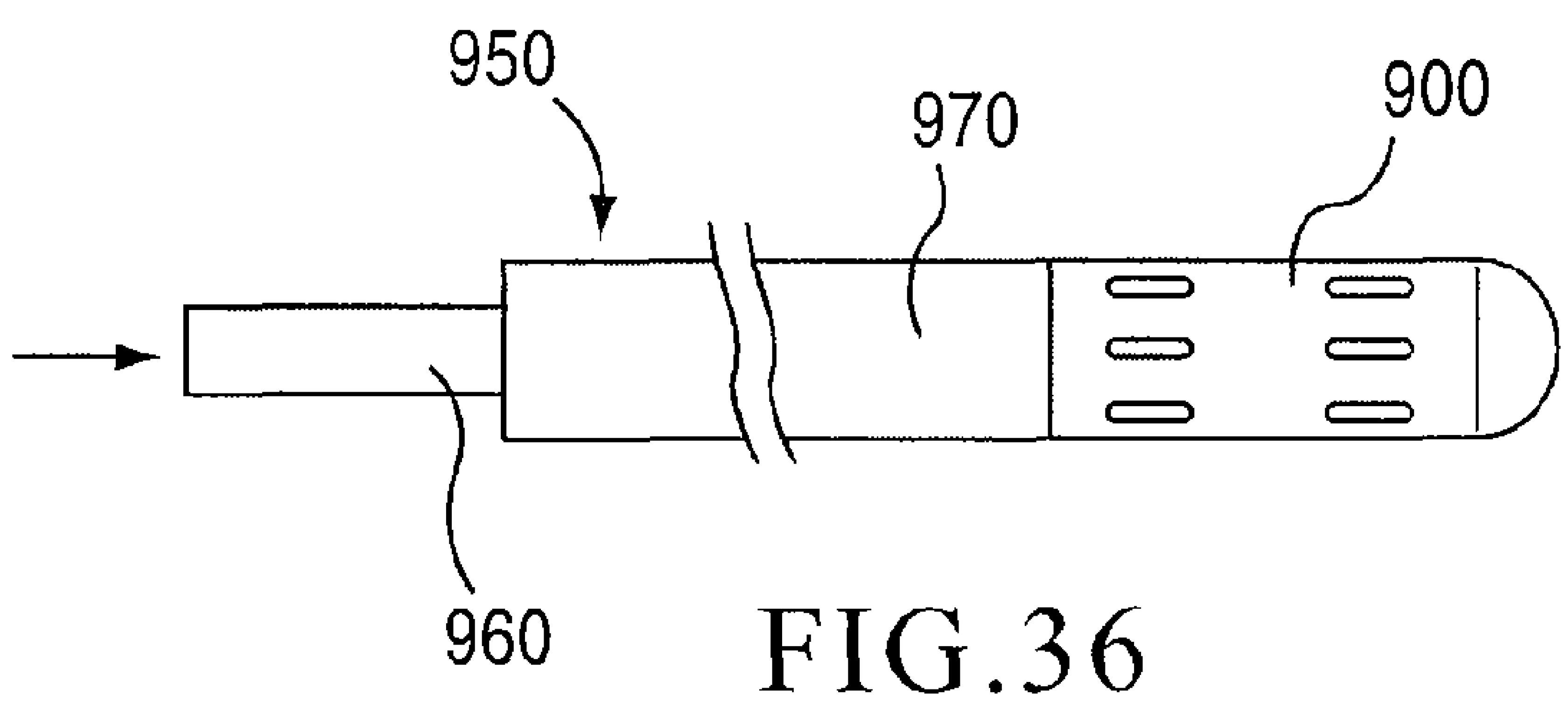


FIG.36

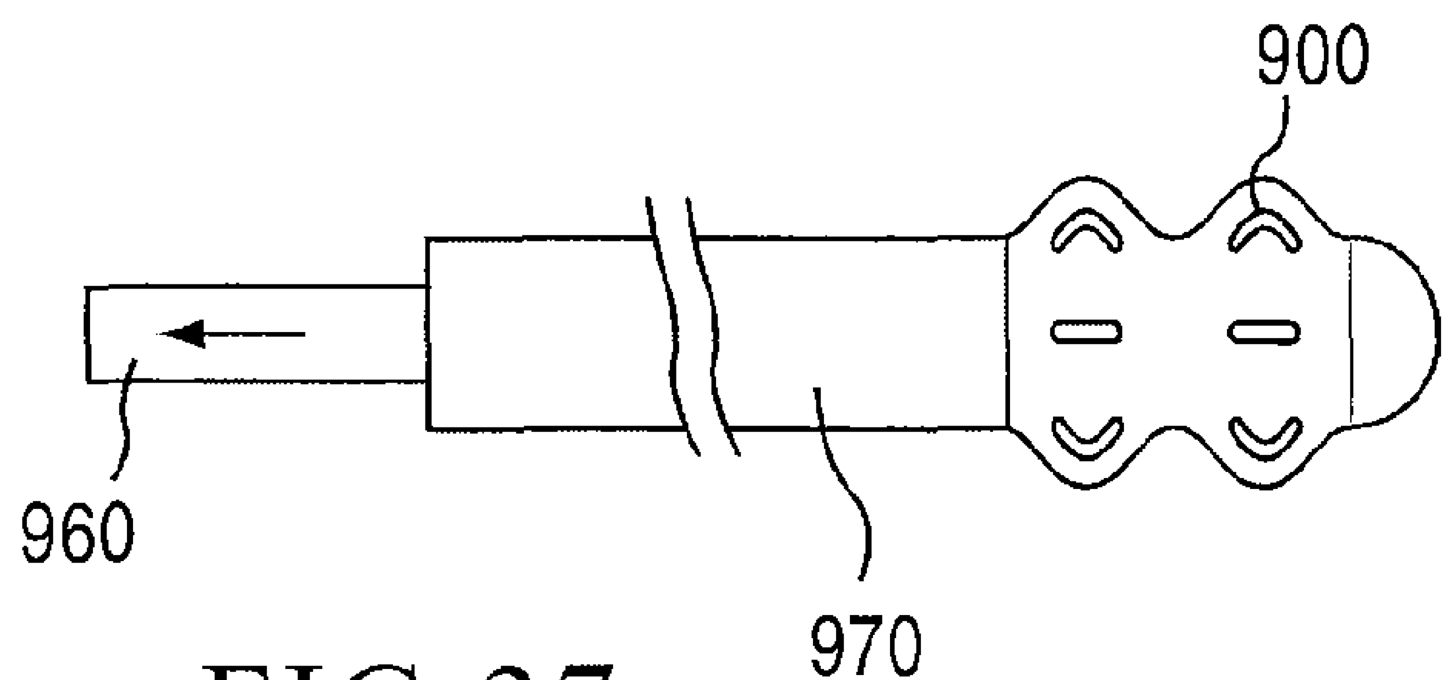


FIG.37

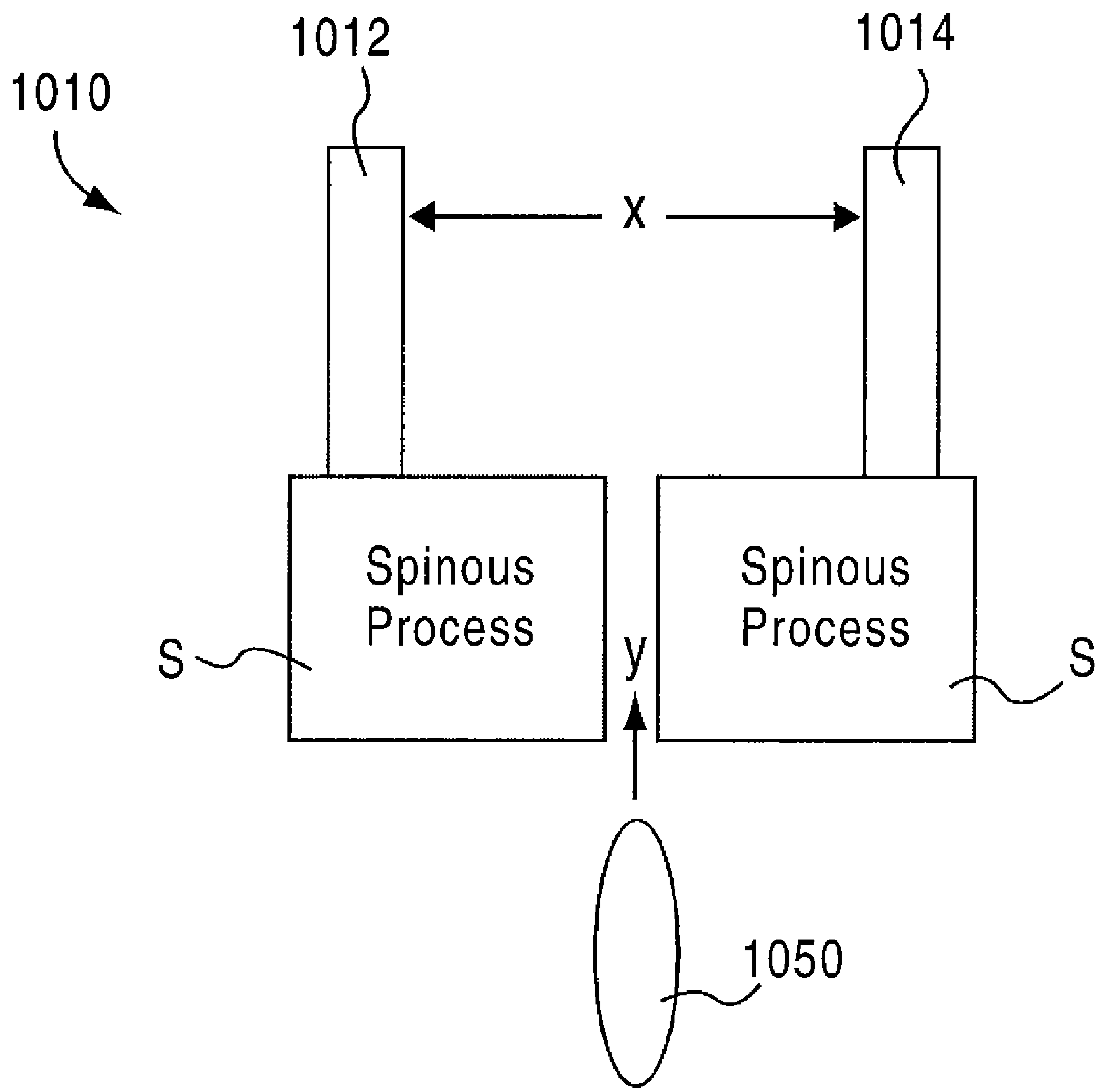
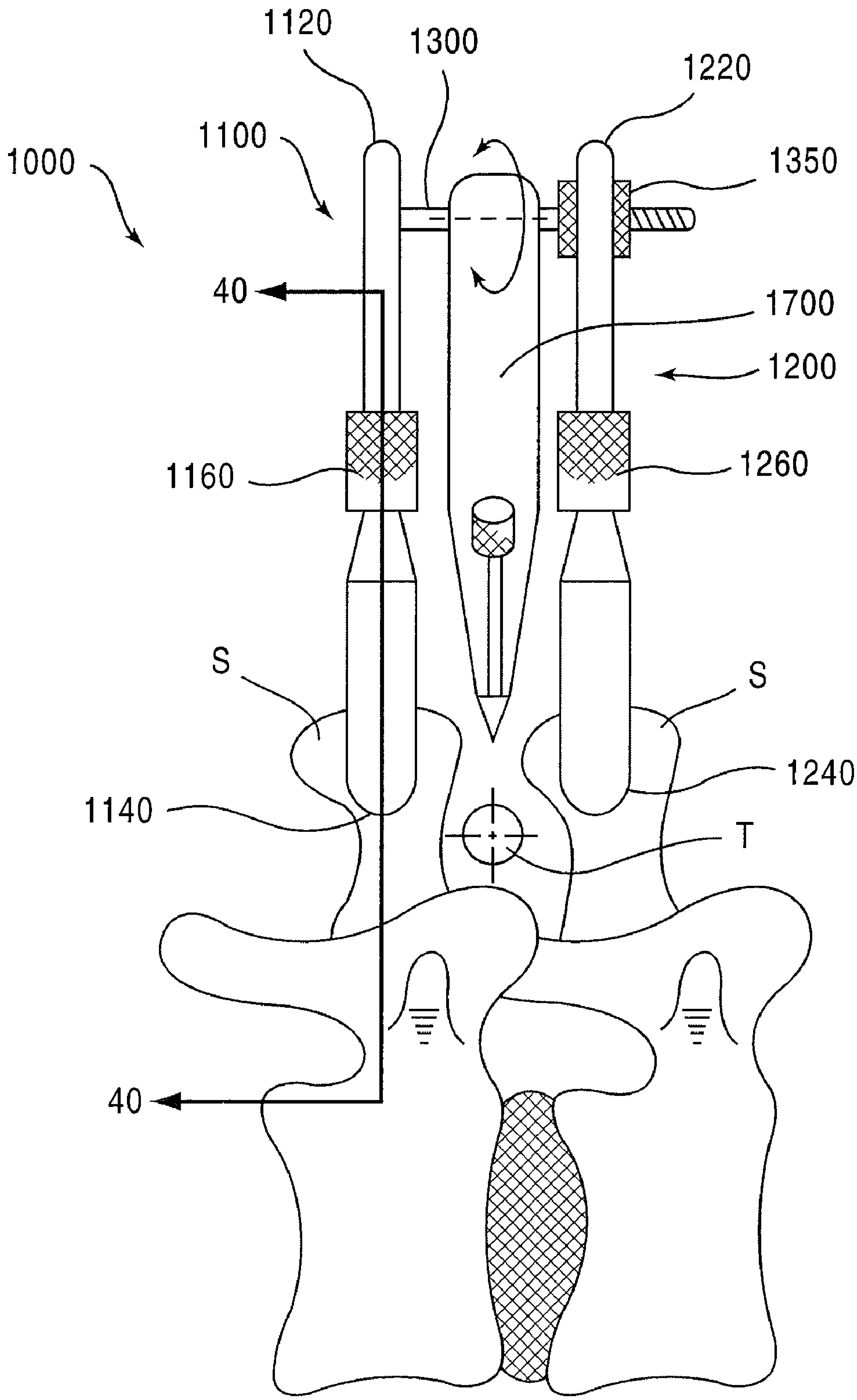


FIG.38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1260
S
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T
40

FIG. 39

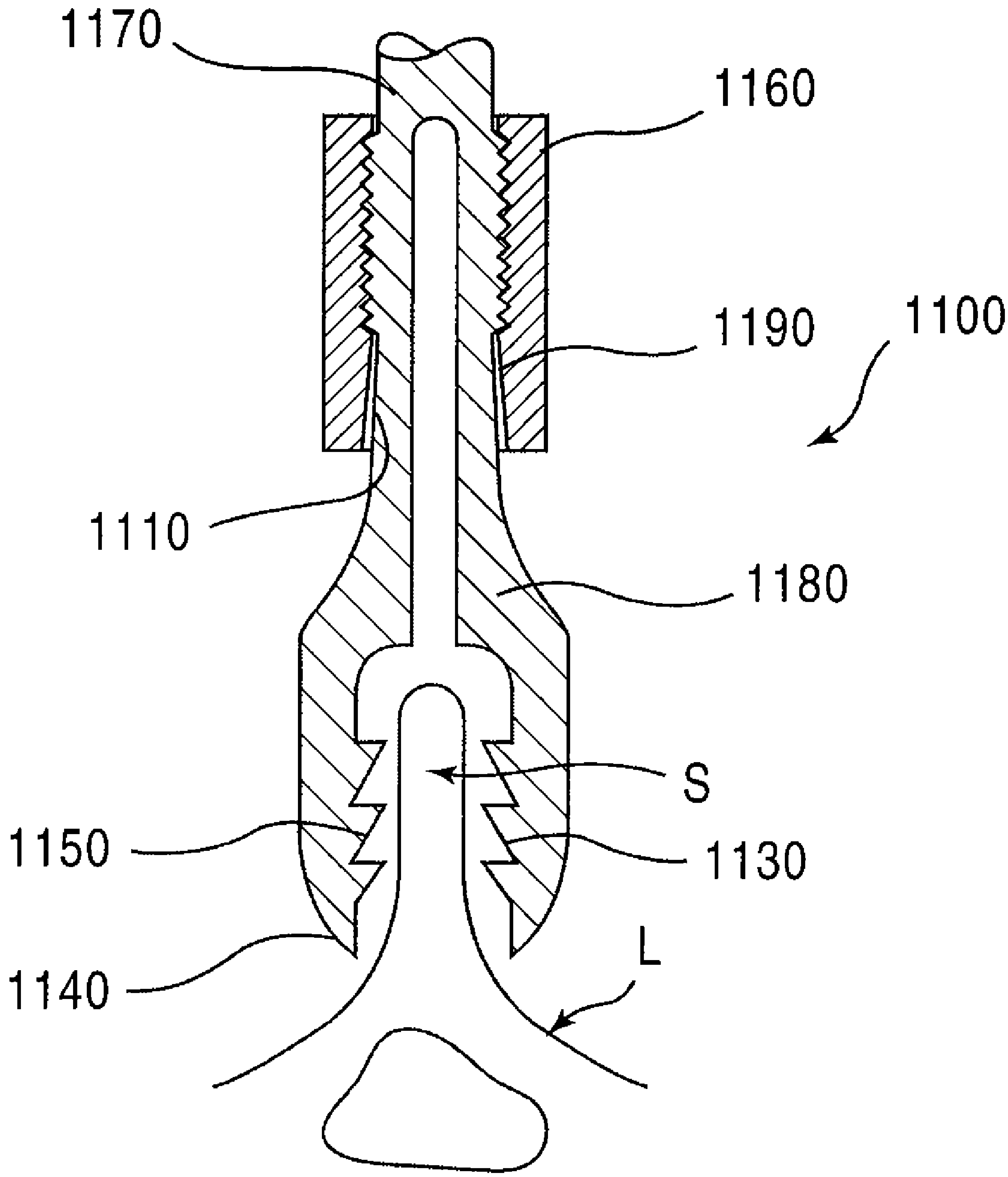

FIG.40

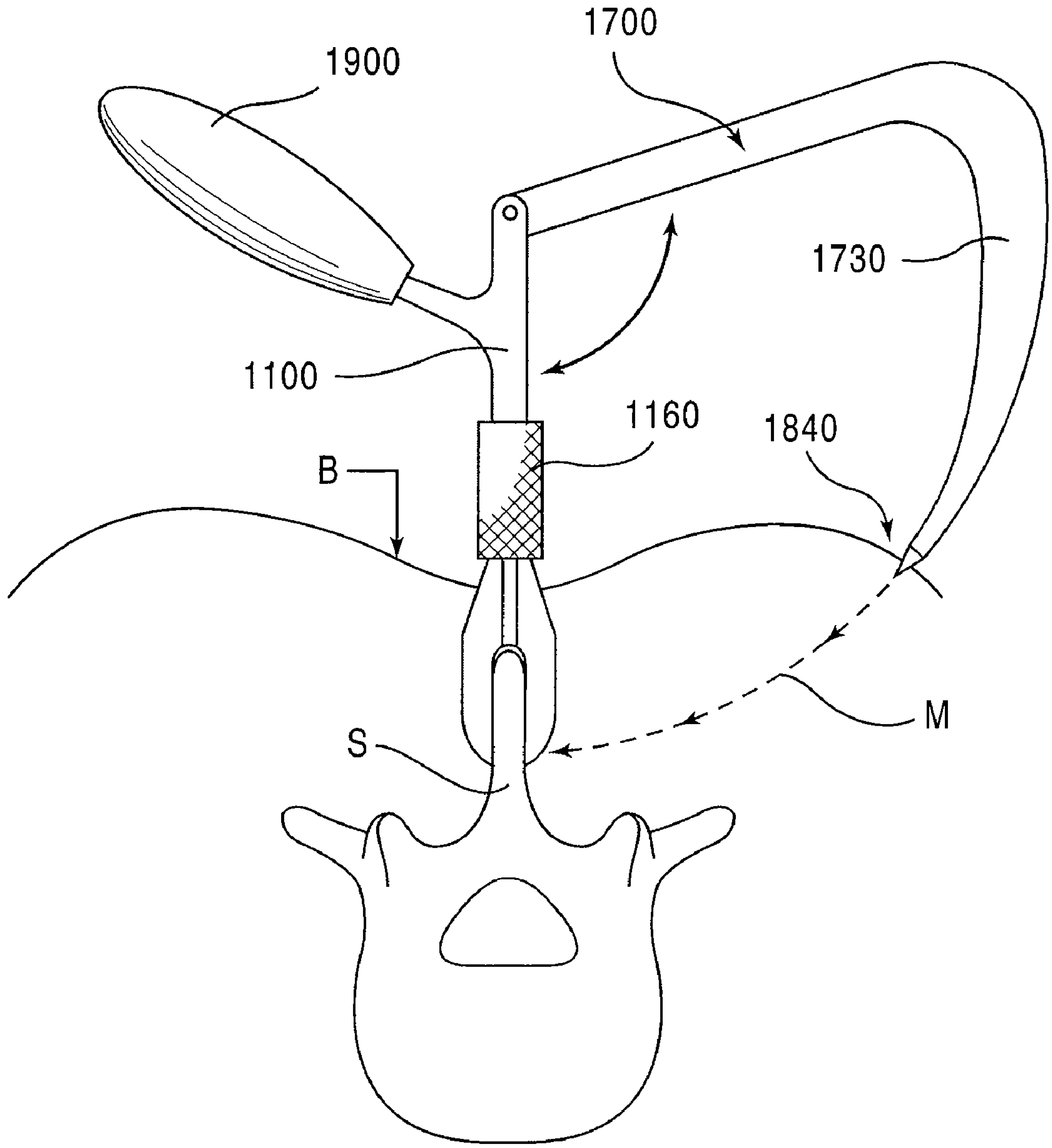

FIG.41

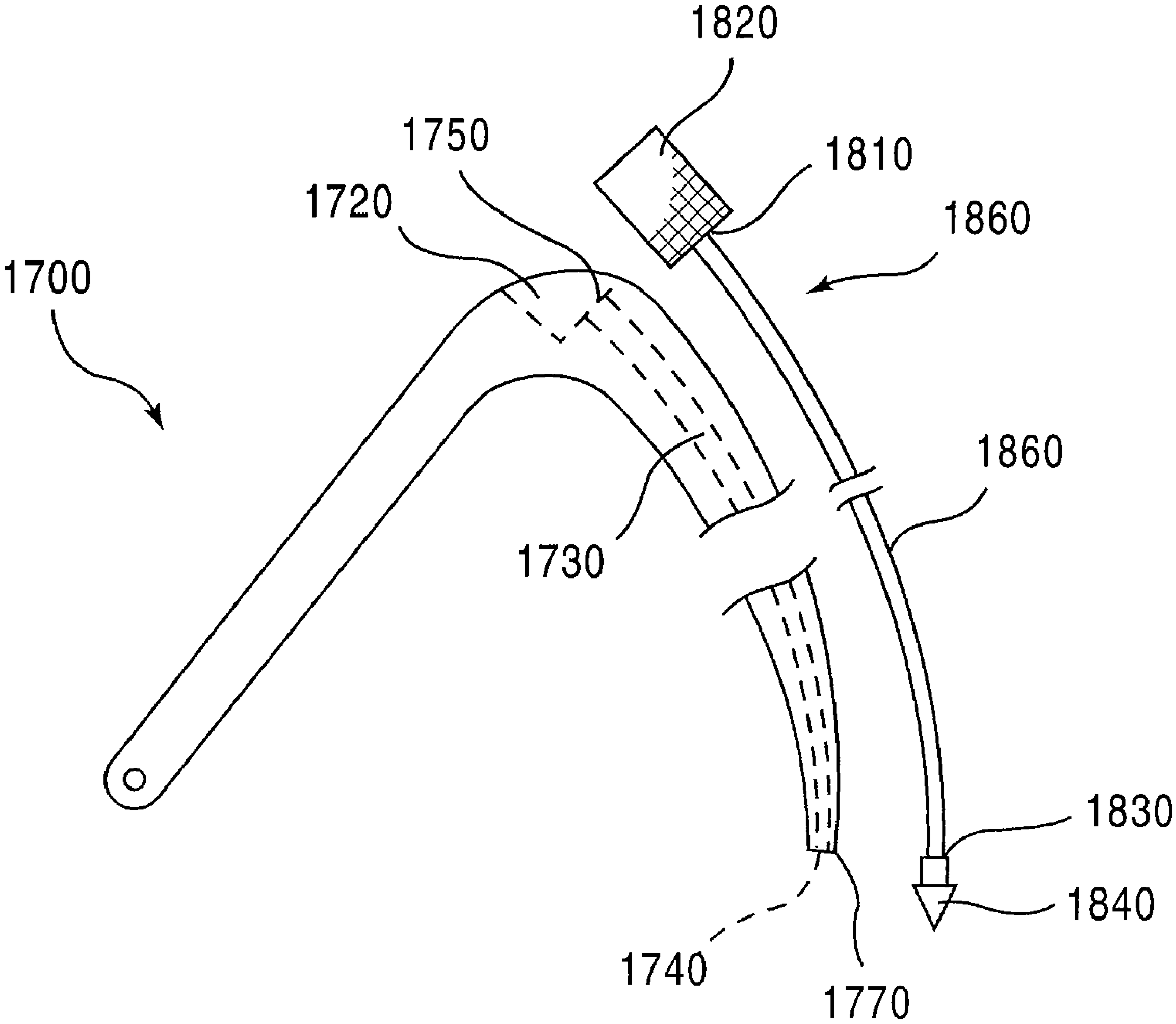
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FIG.42

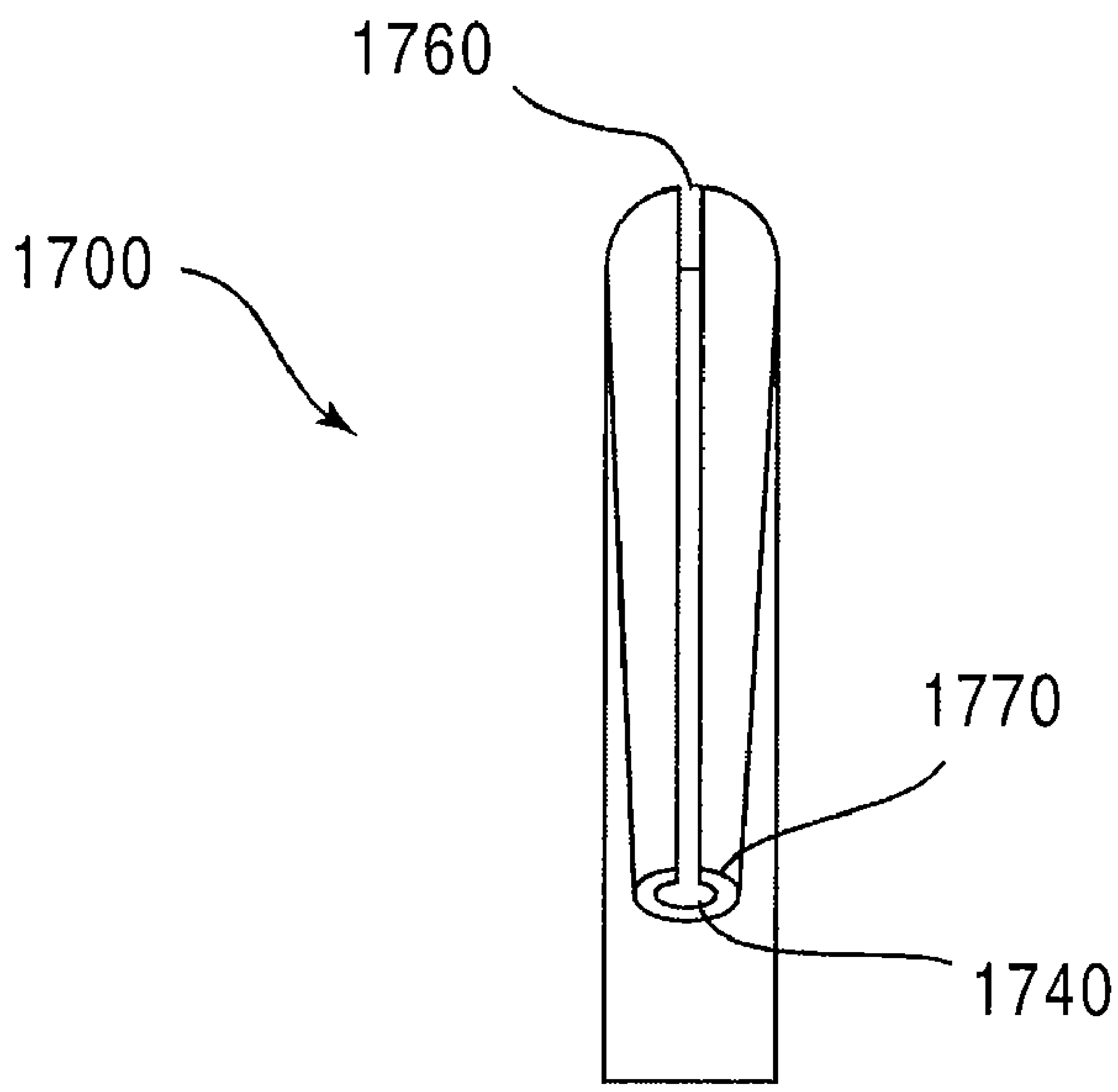
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FIG.43

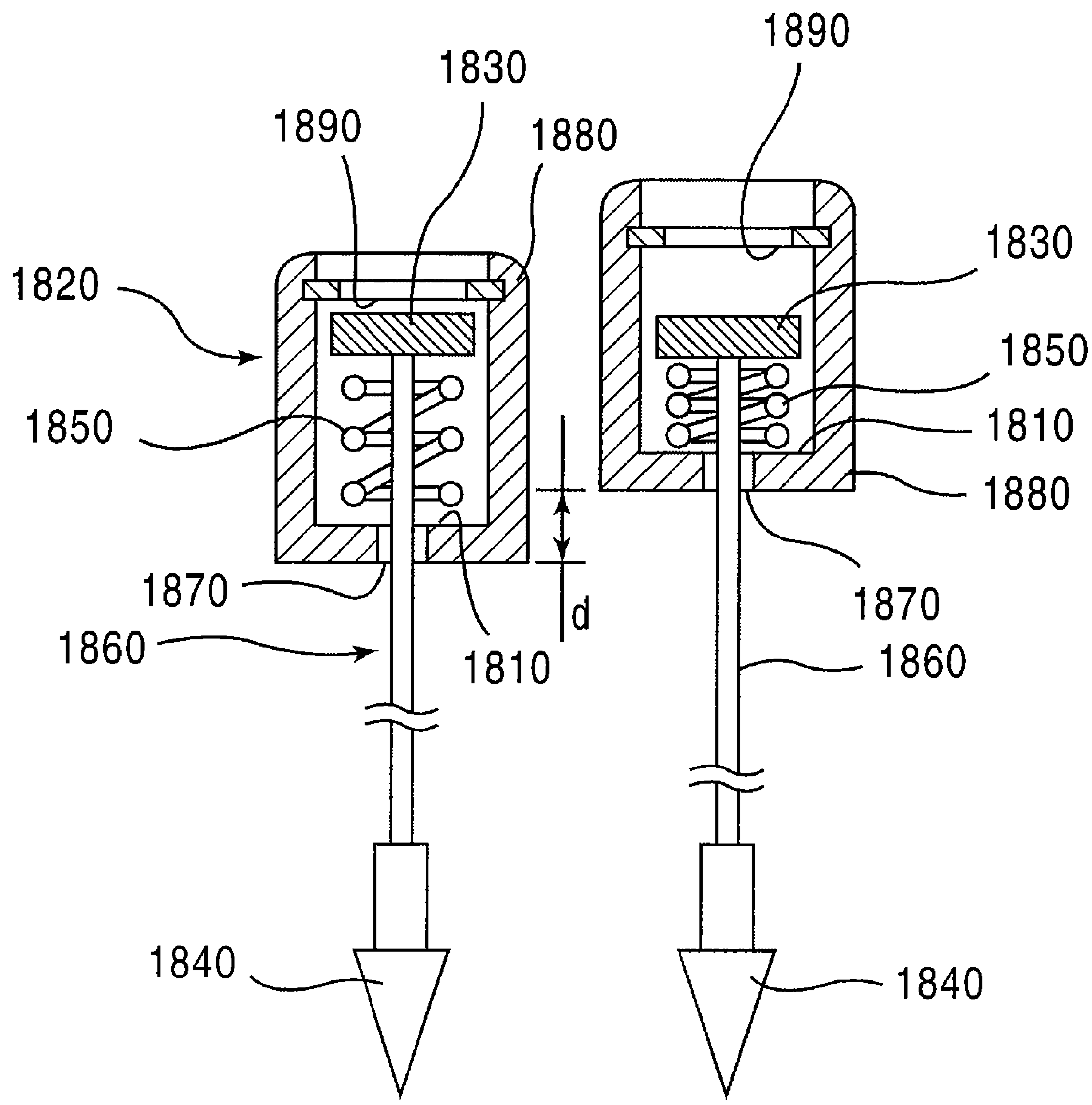


FIG.44 FIG.45

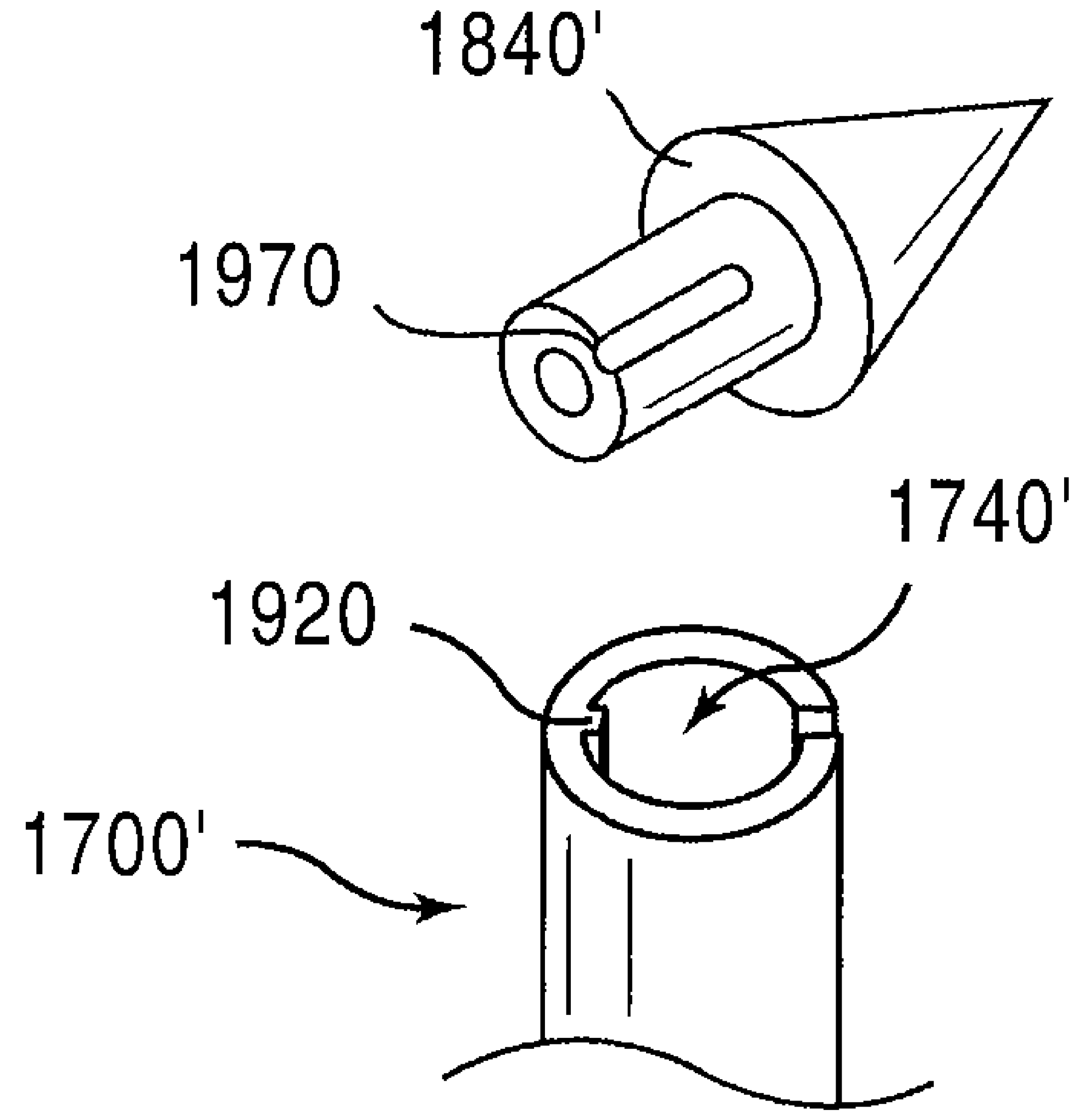


FIG.46

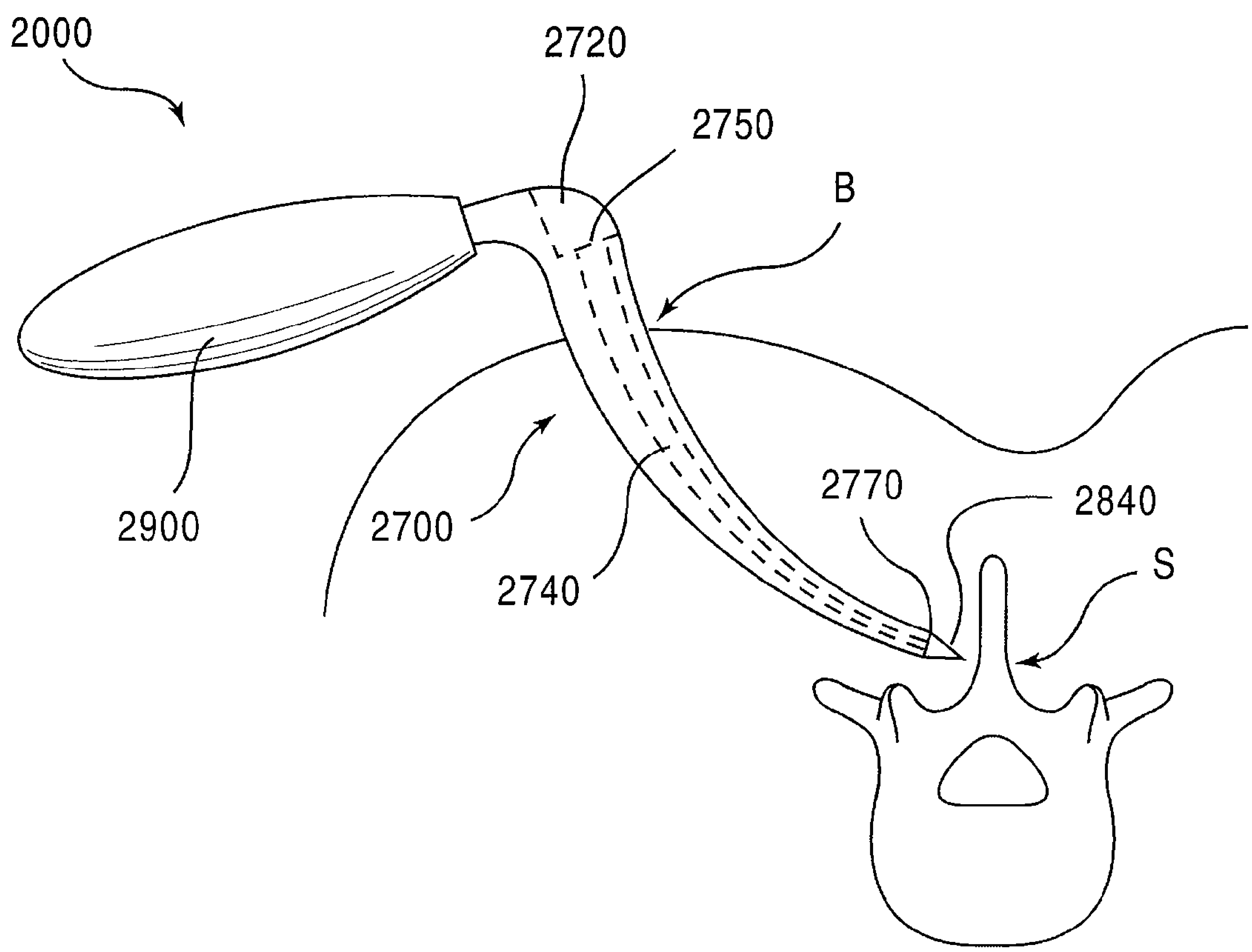


FIG.47

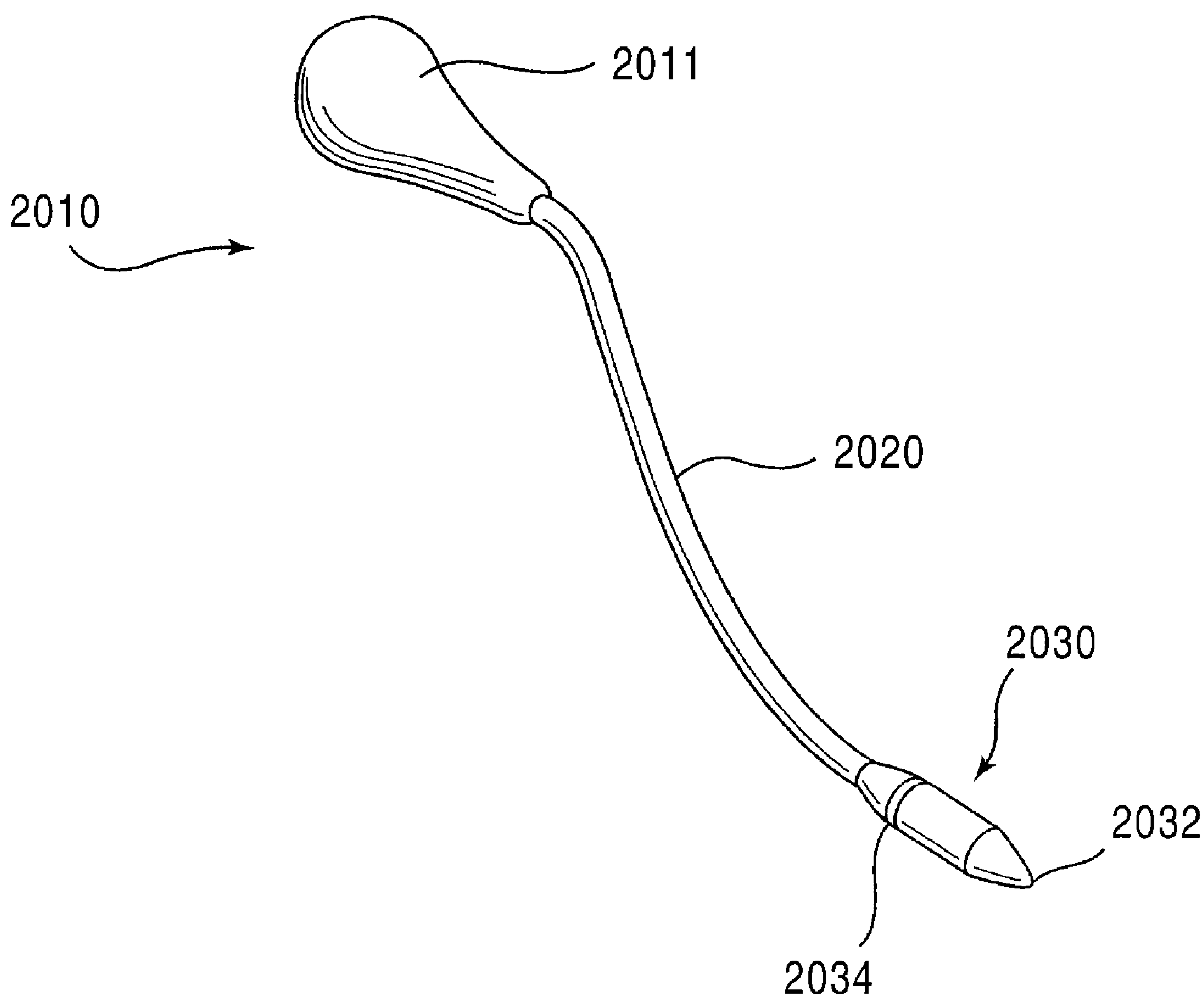


FIG.48

FIG.49A

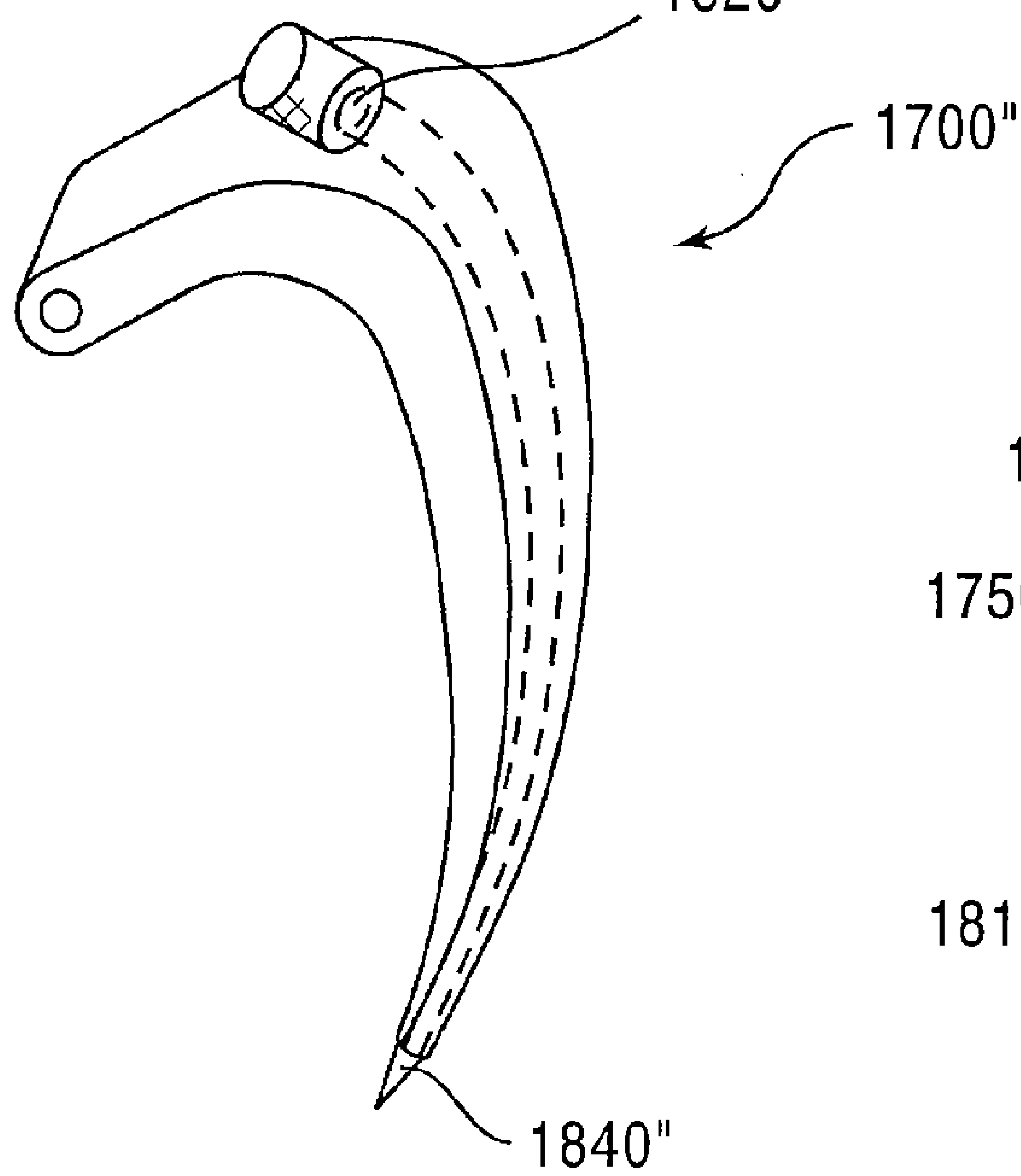
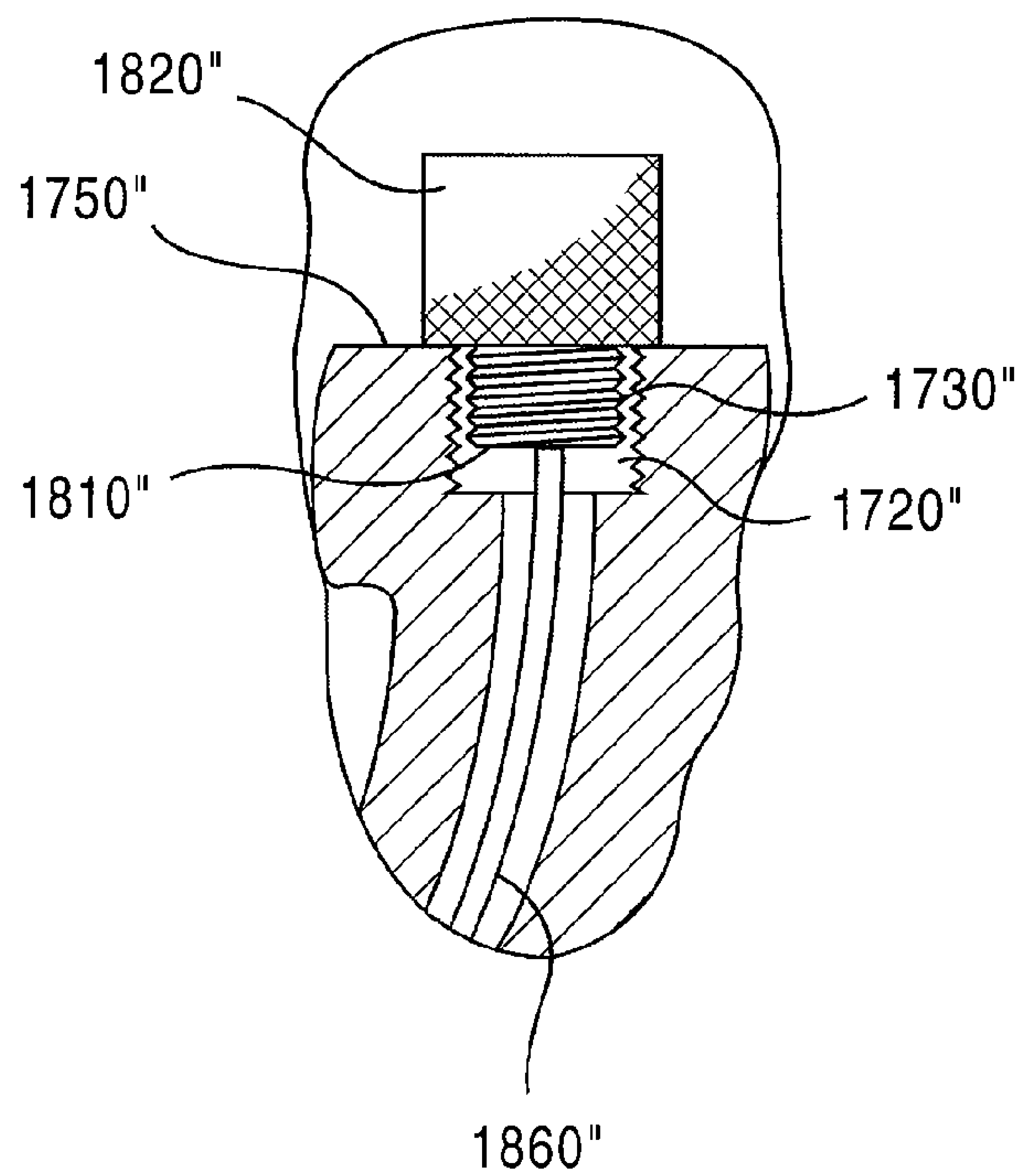


FIG.49B



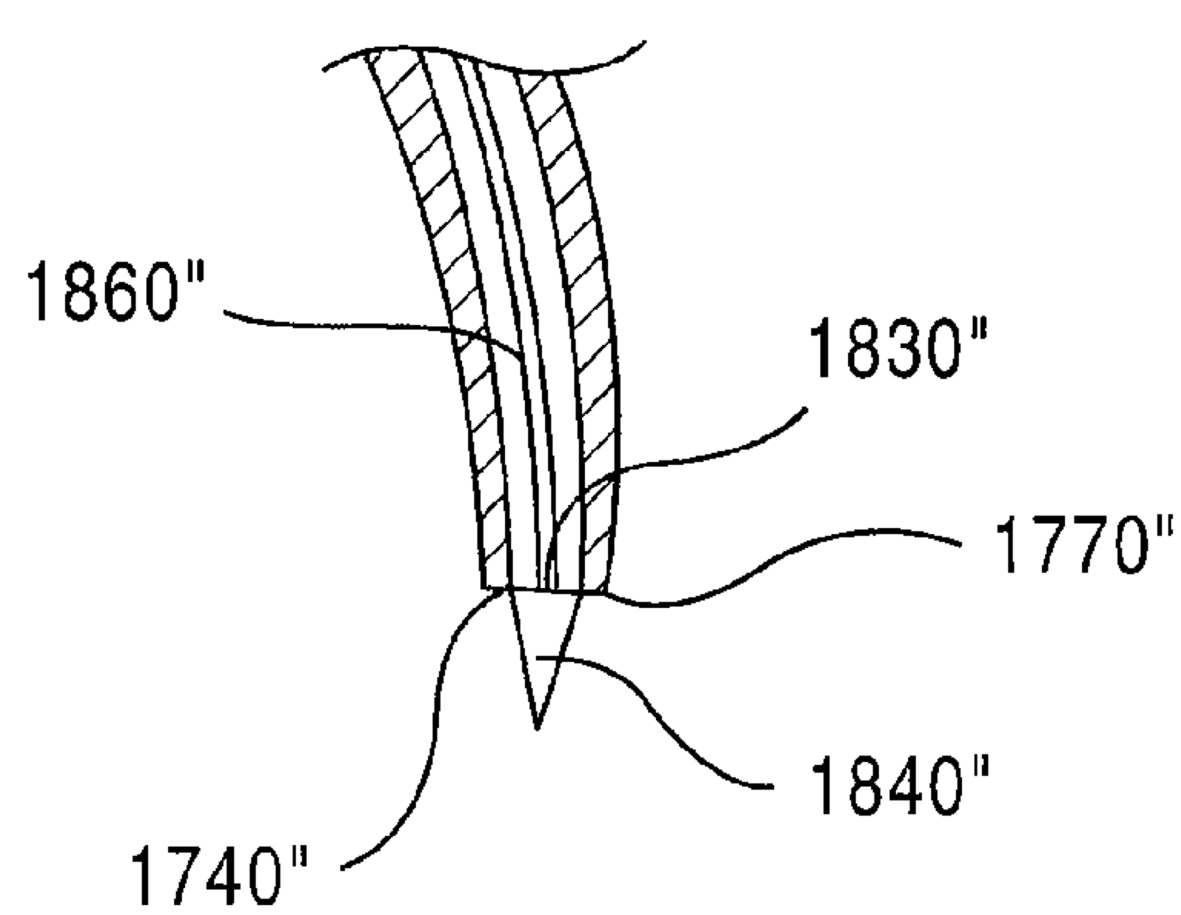


FIG.49C

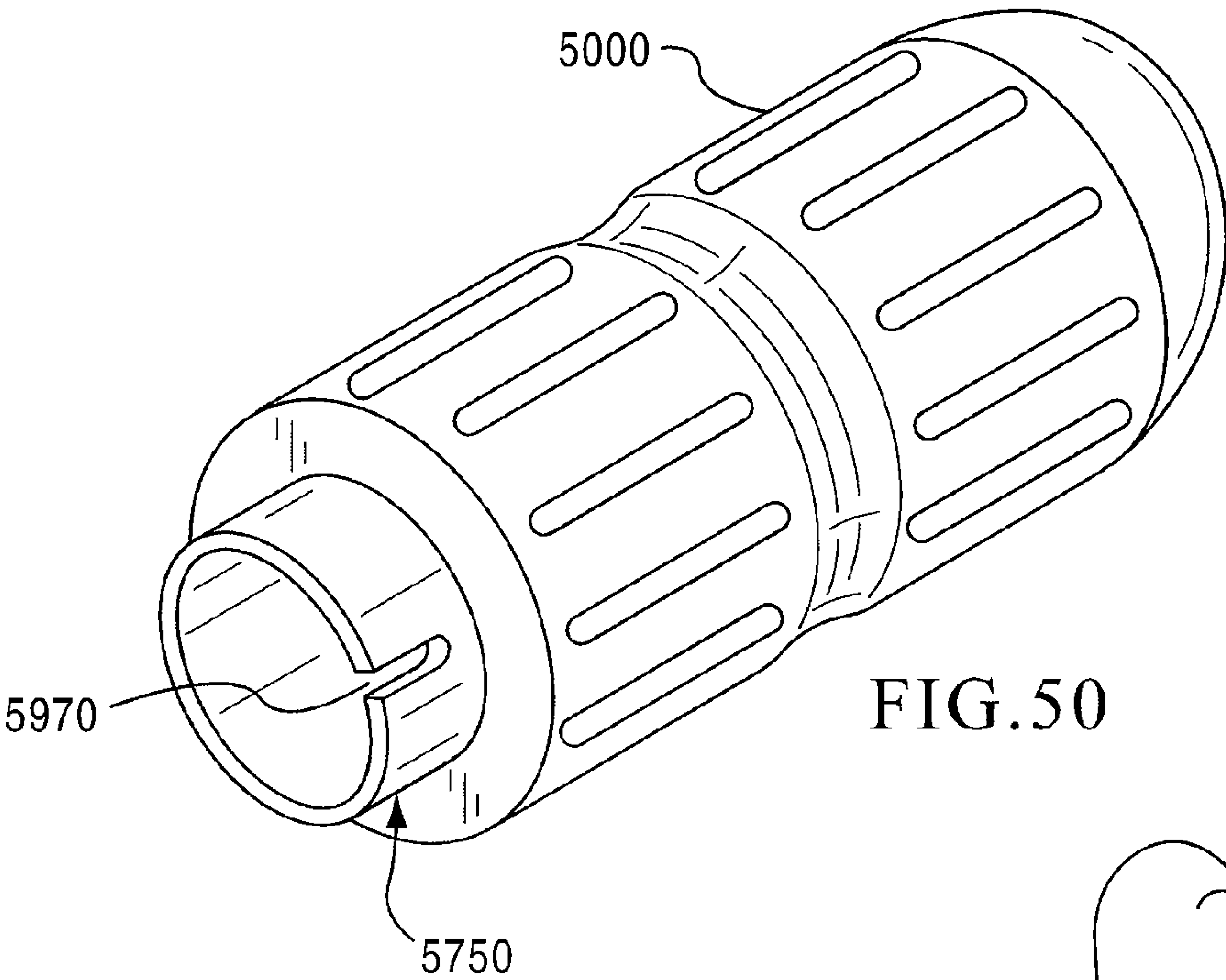


FIG.50

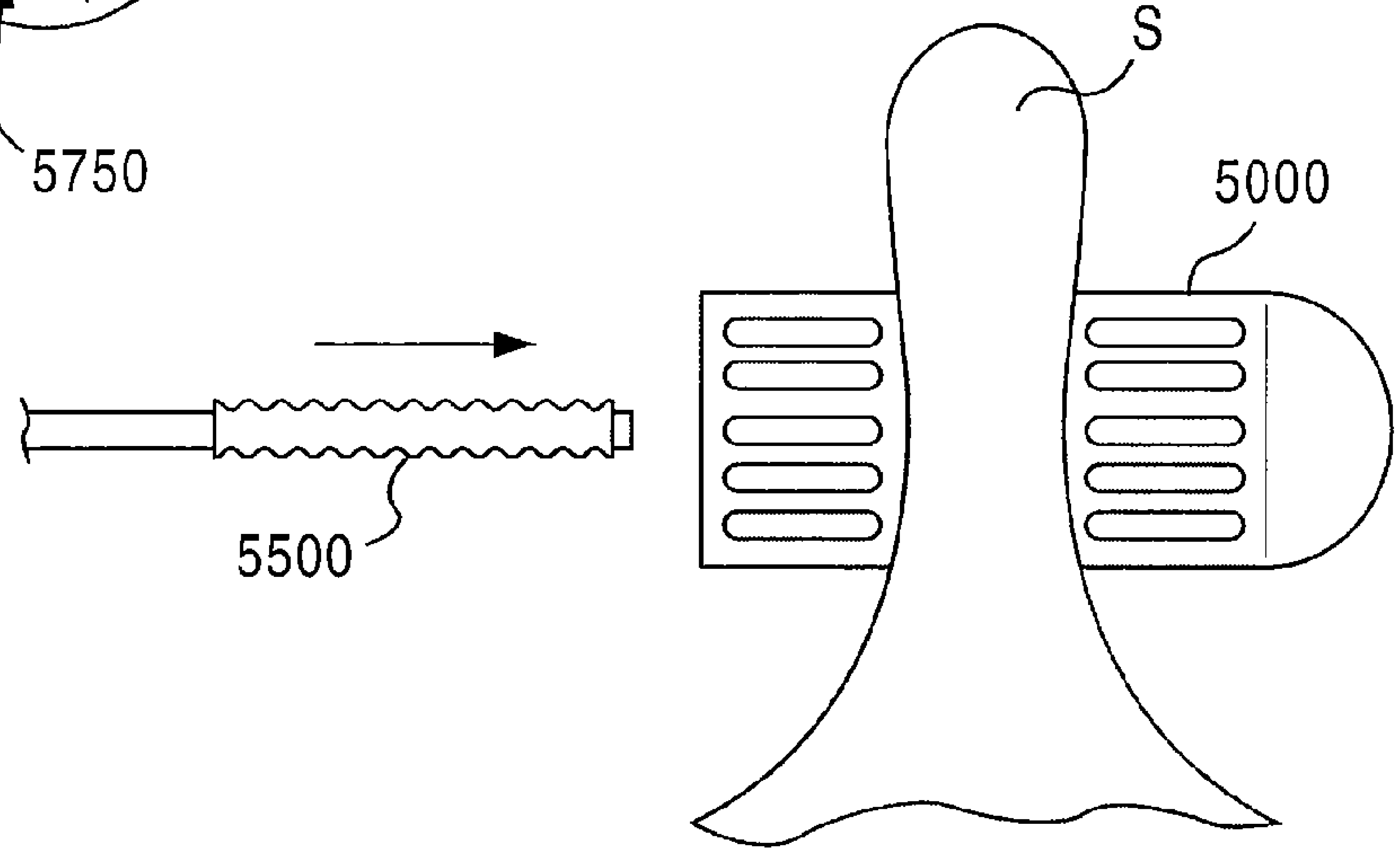


FIG.51

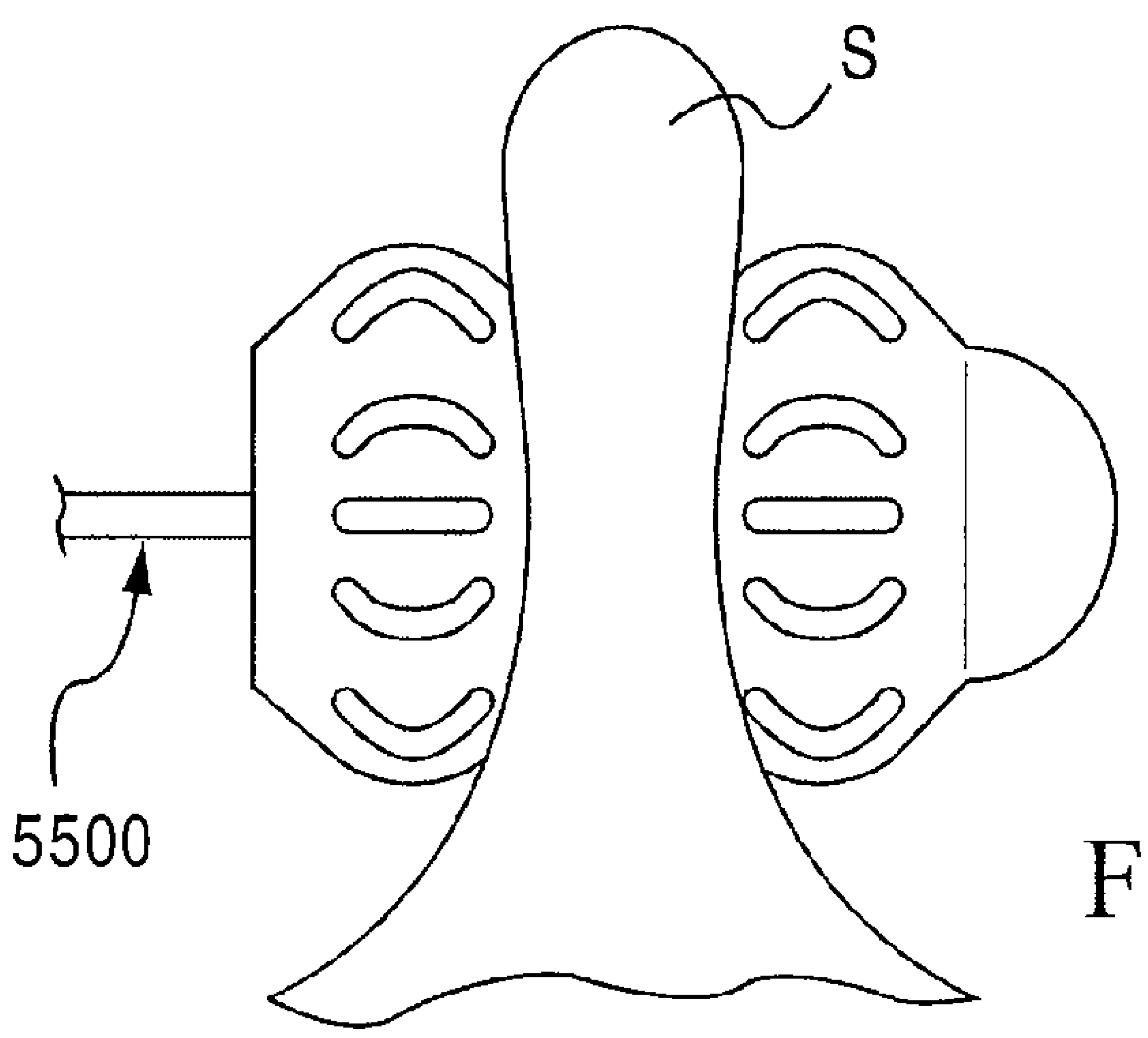


FIG.52

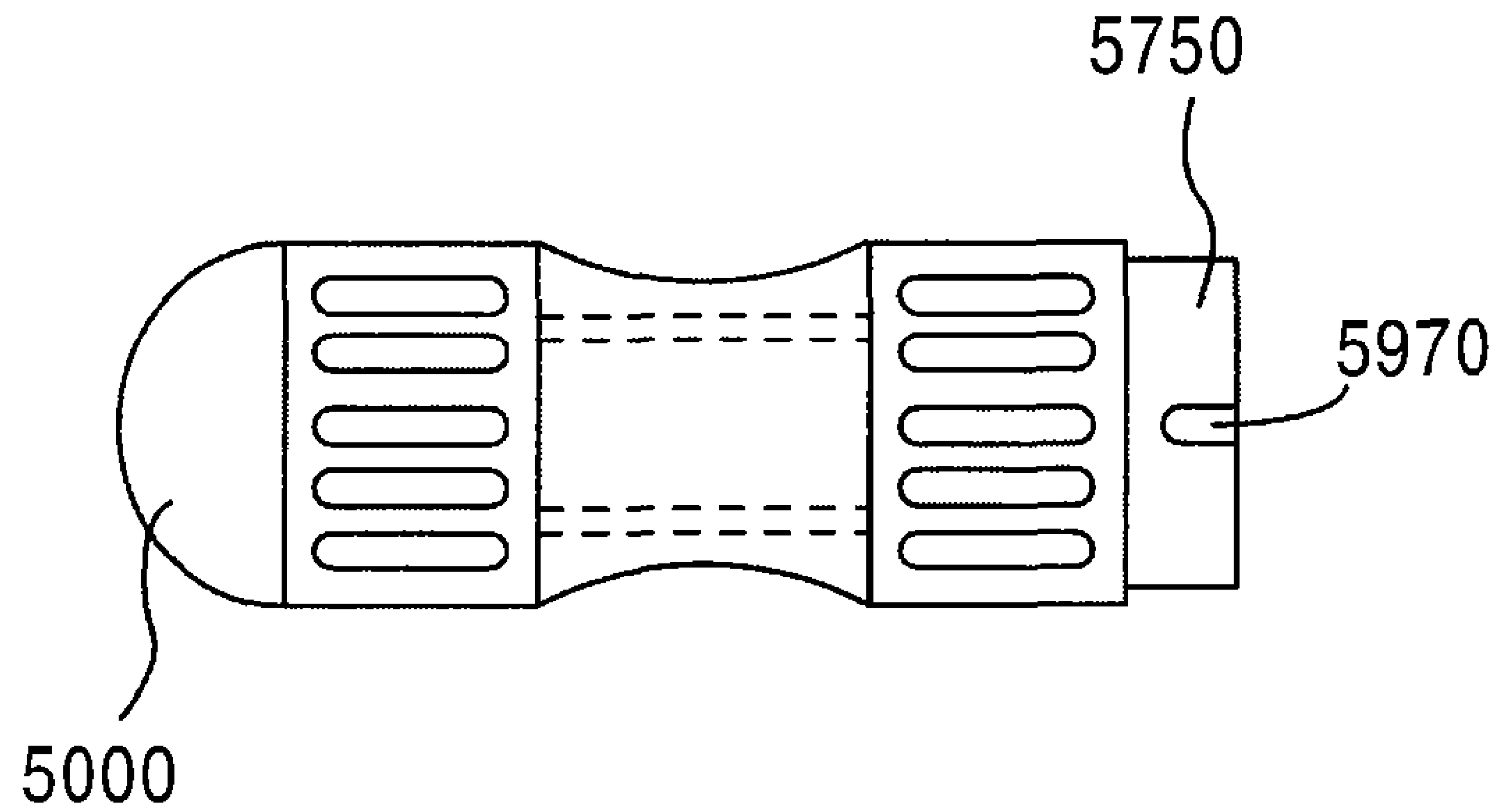


FIG.53

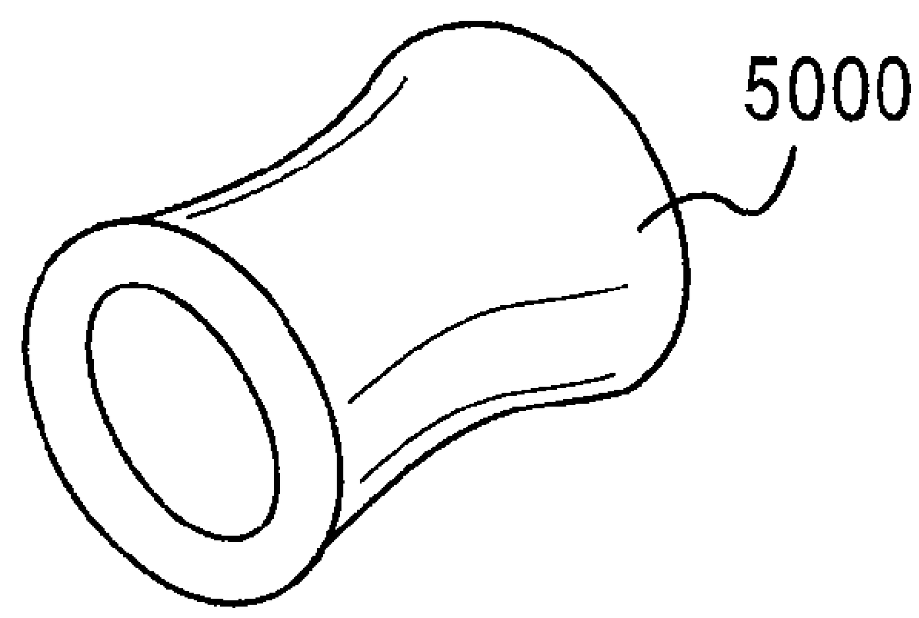


FIG.54

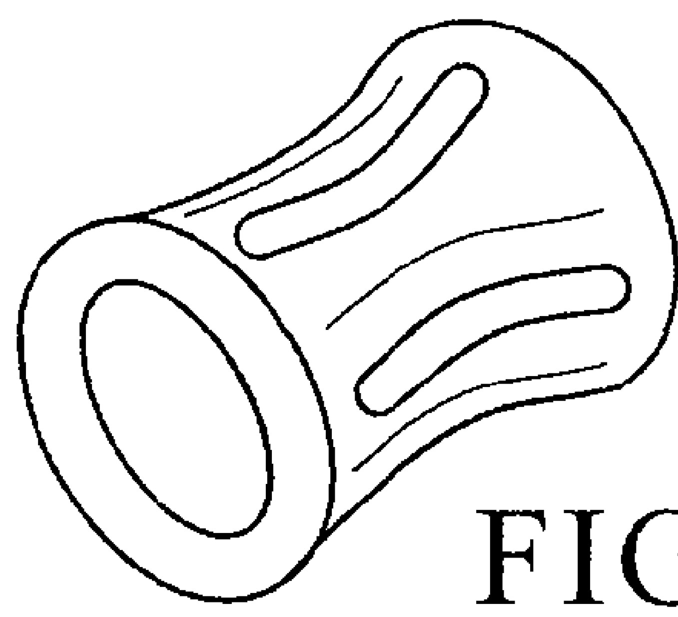


FIG.55

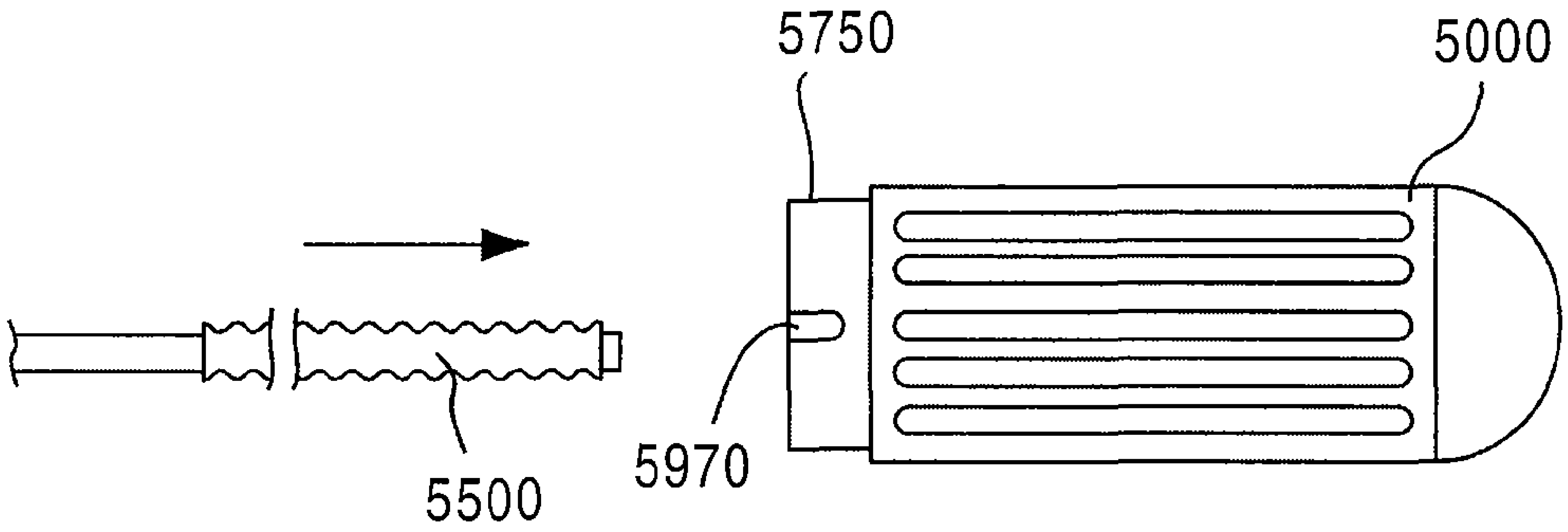


FIG.56

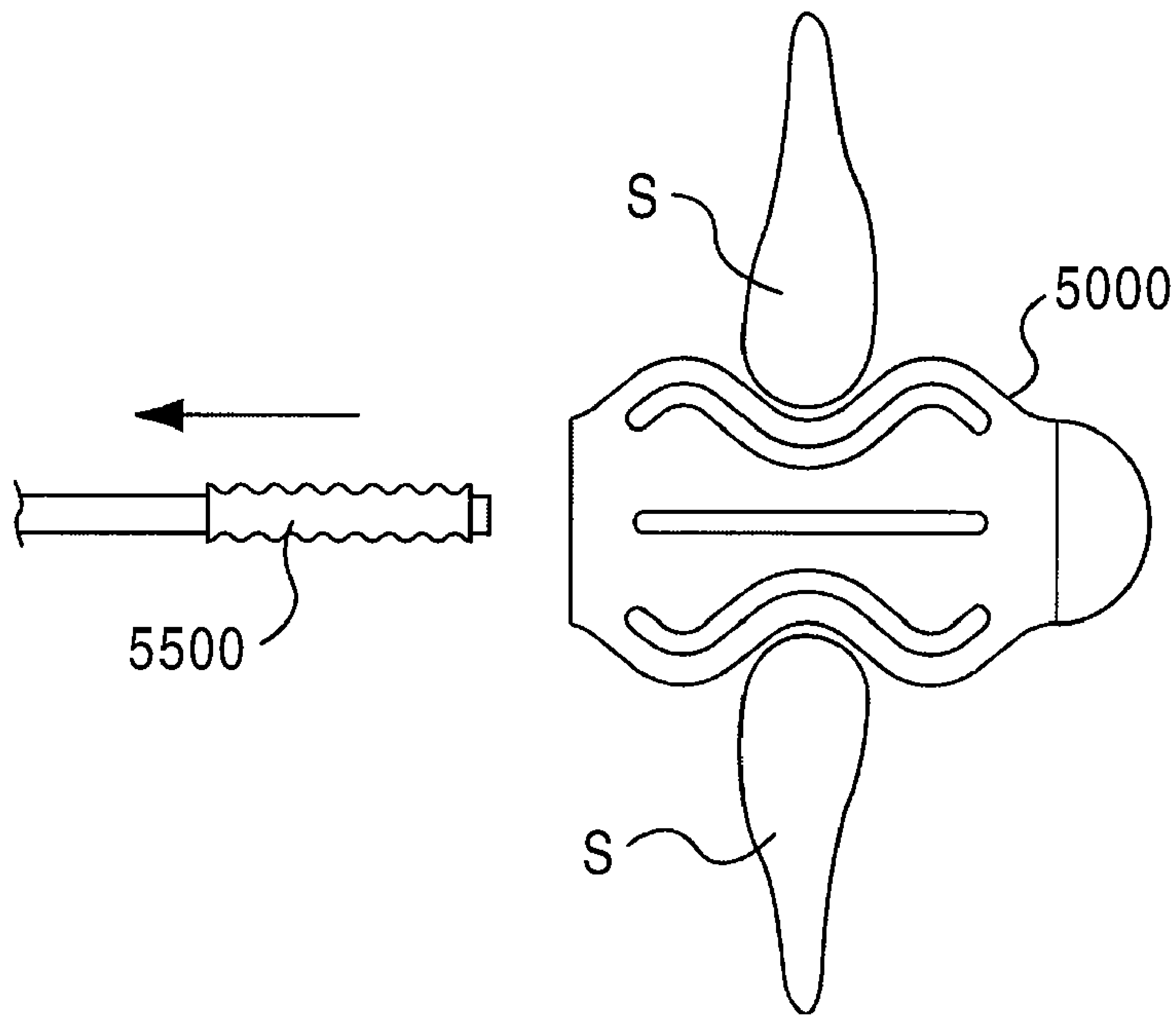


FIG.57

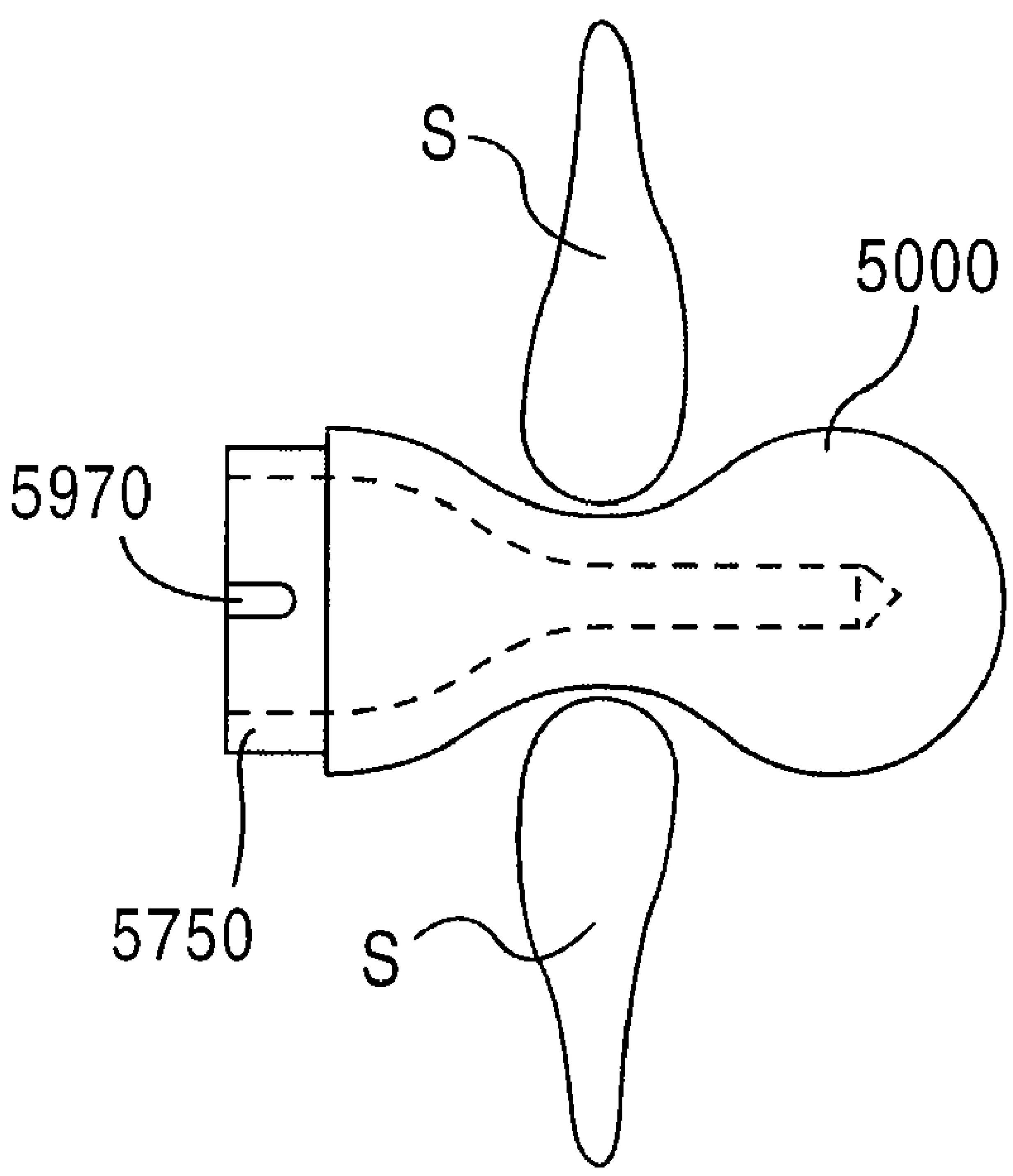


FIG.58

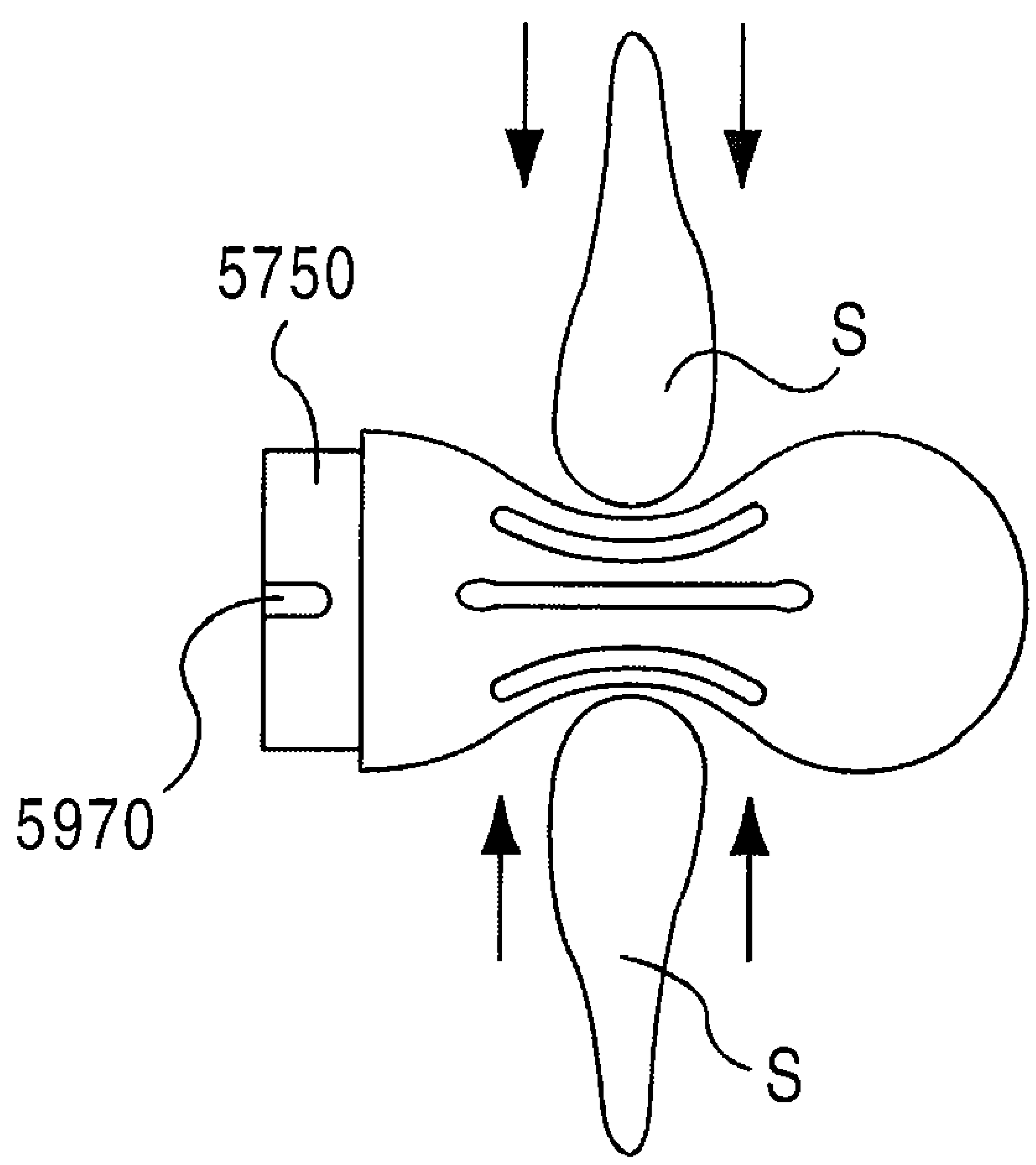


FIG.59

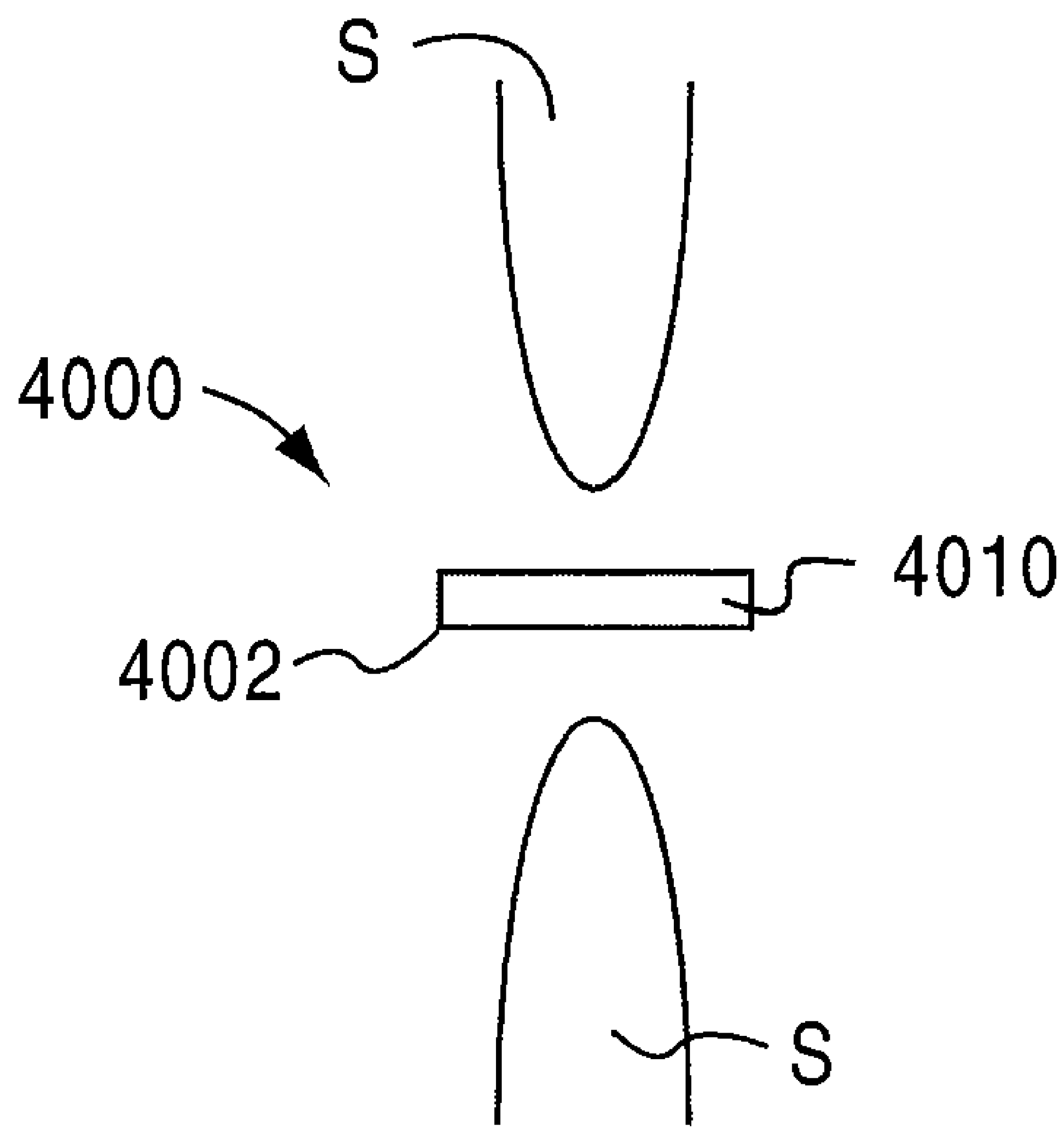


FIG.60A

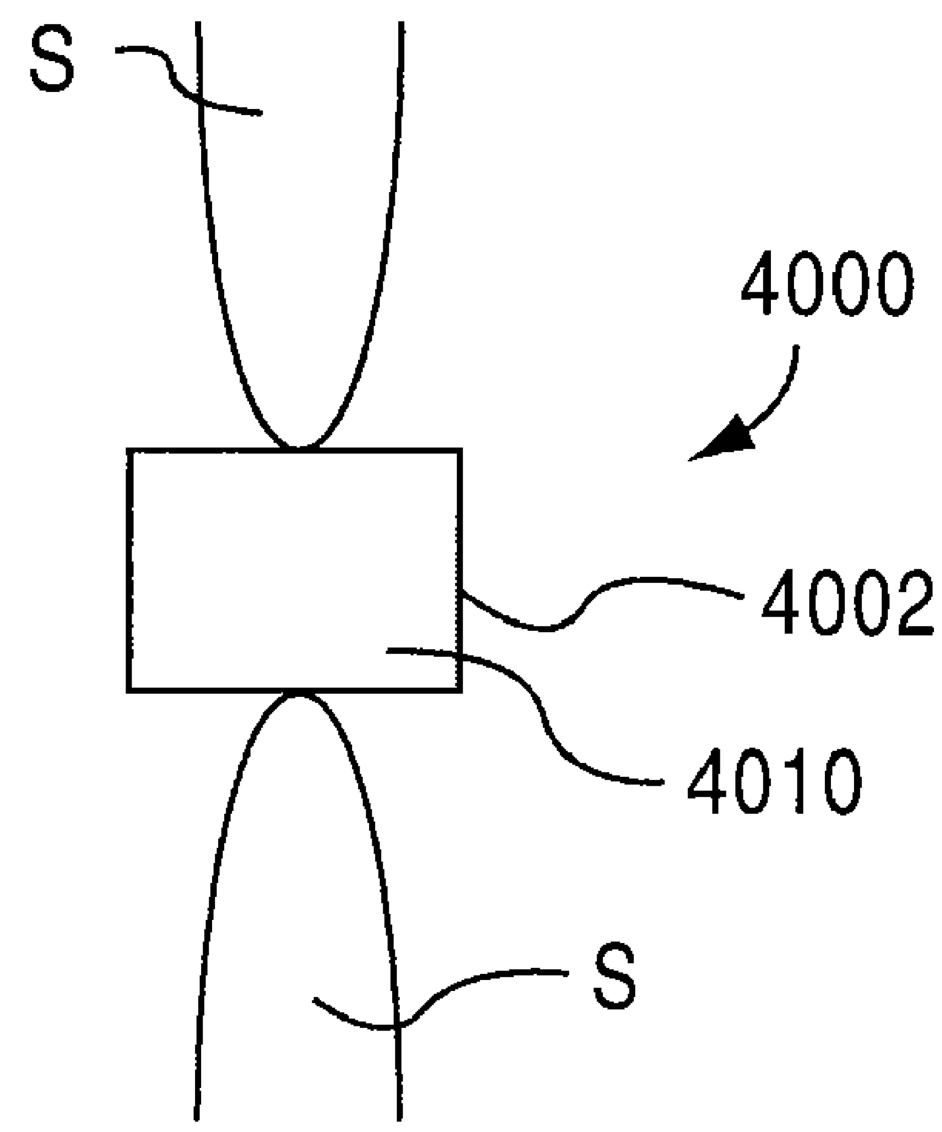


FIG.60B

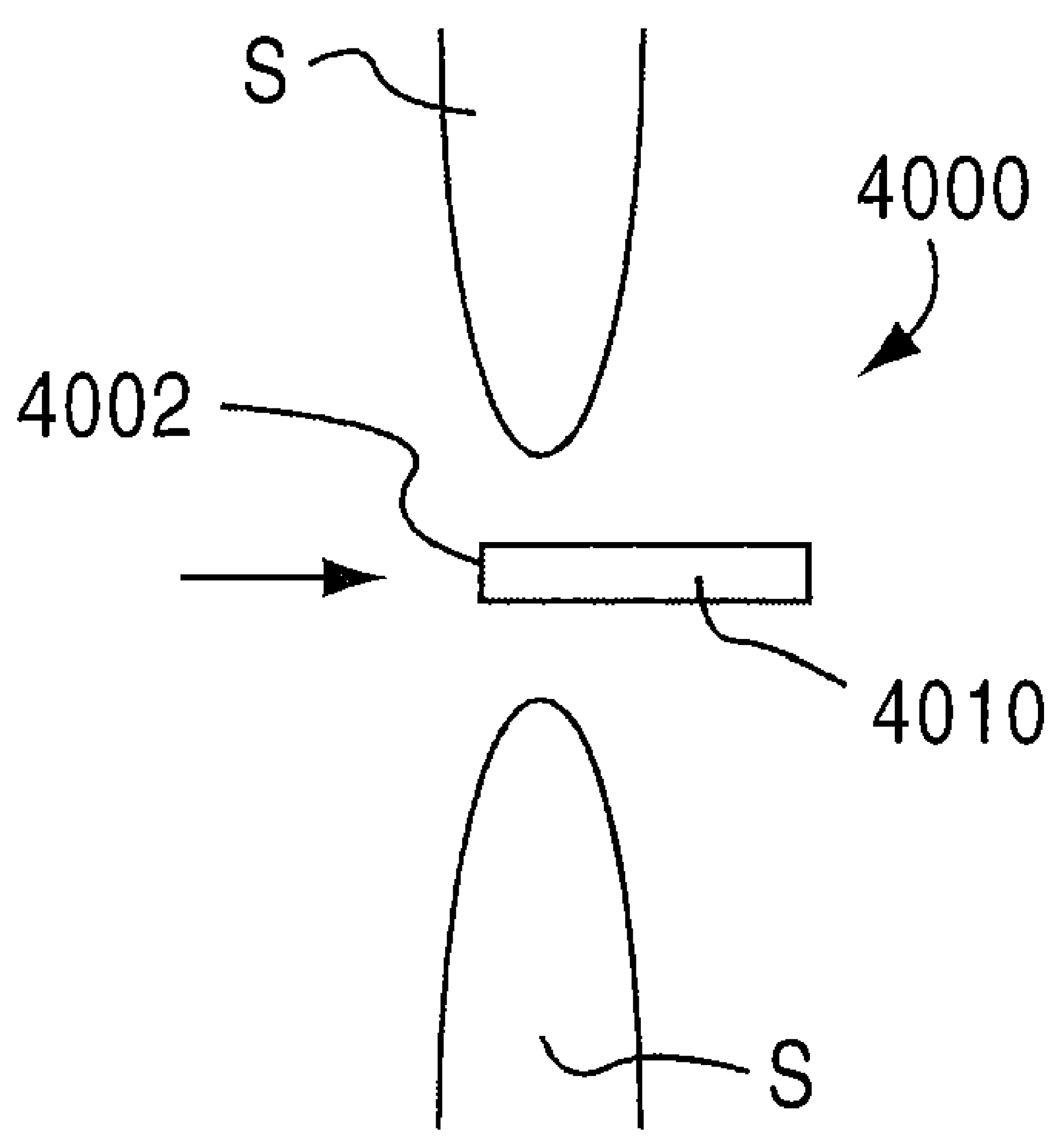


FIG.60C

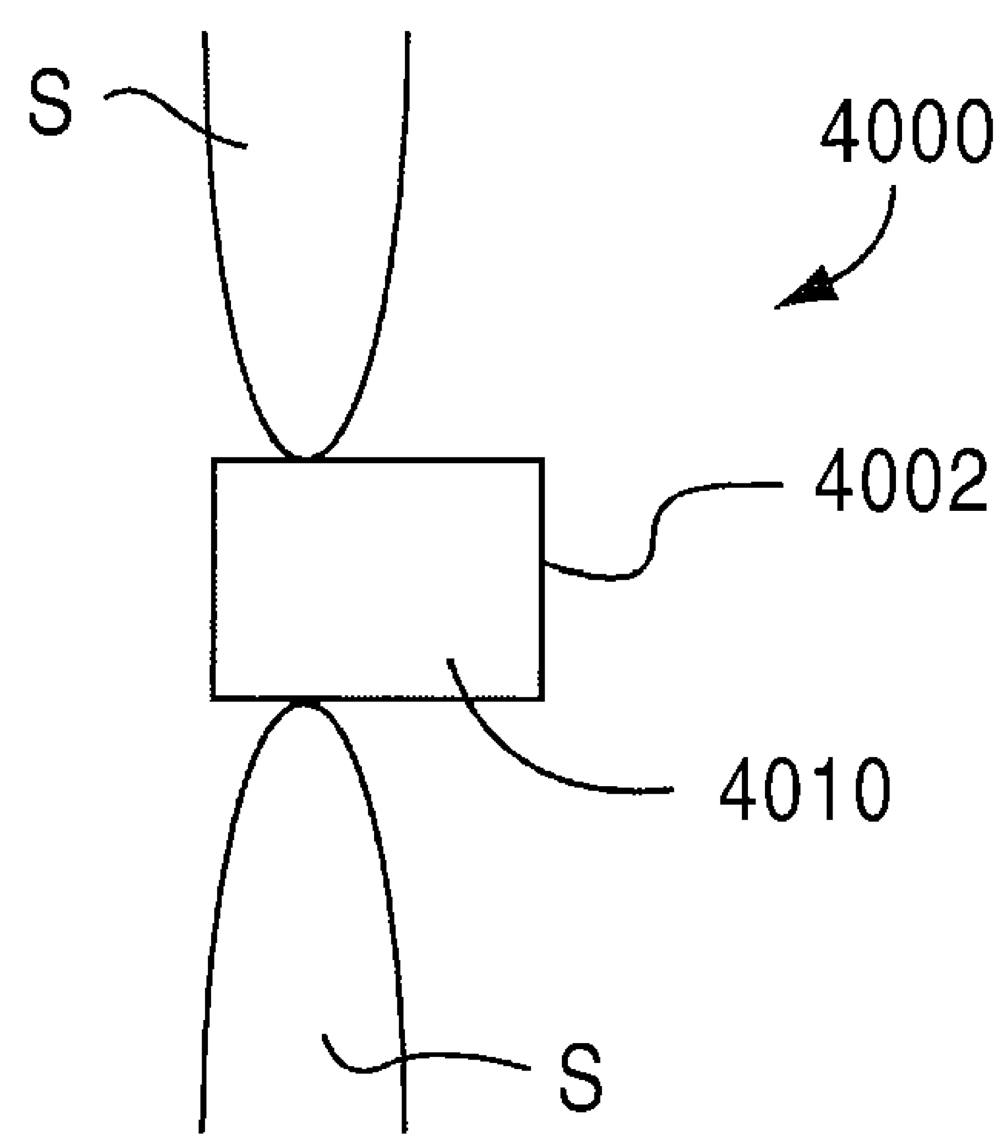


FIG.60D

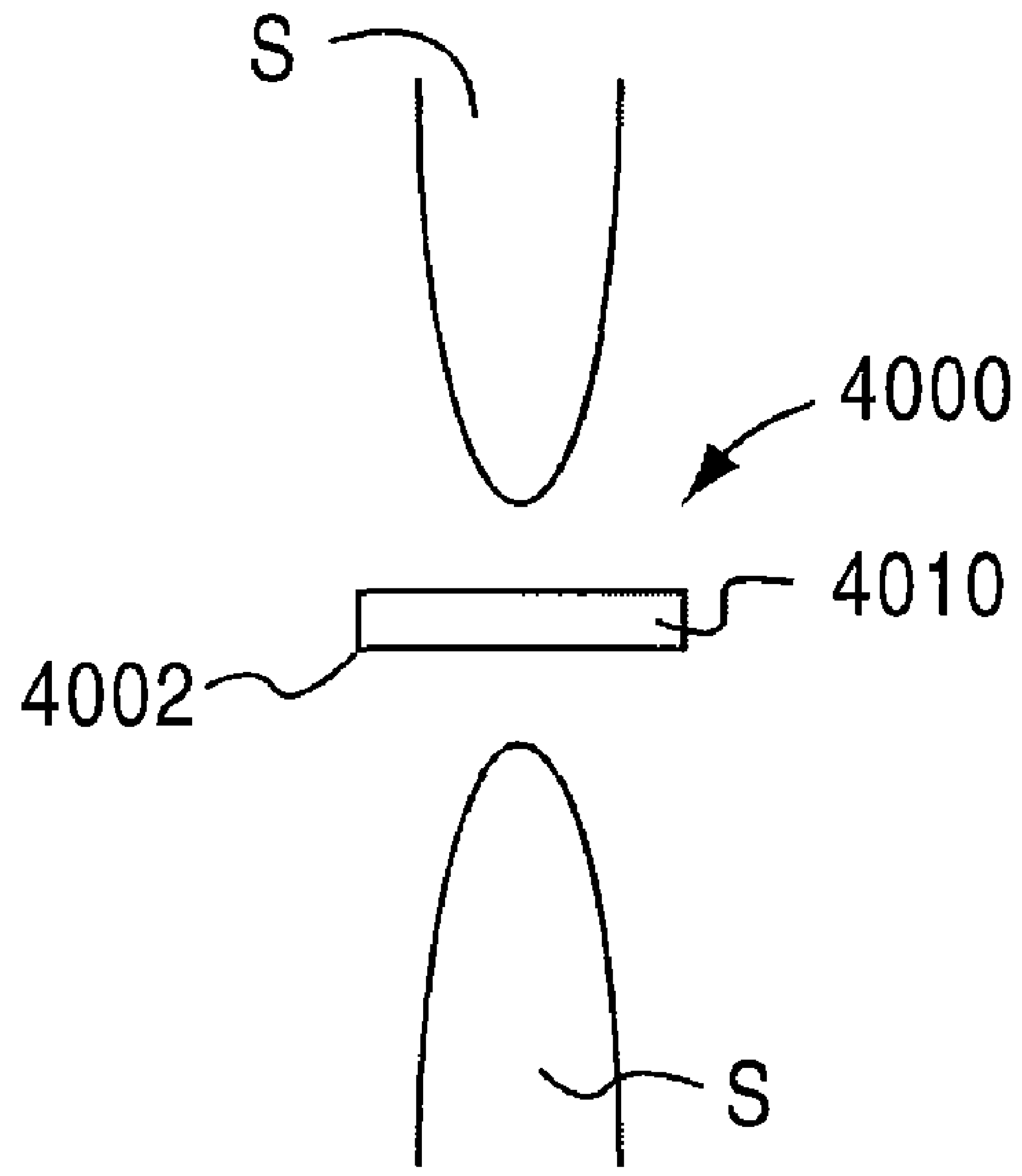


FIG.61A

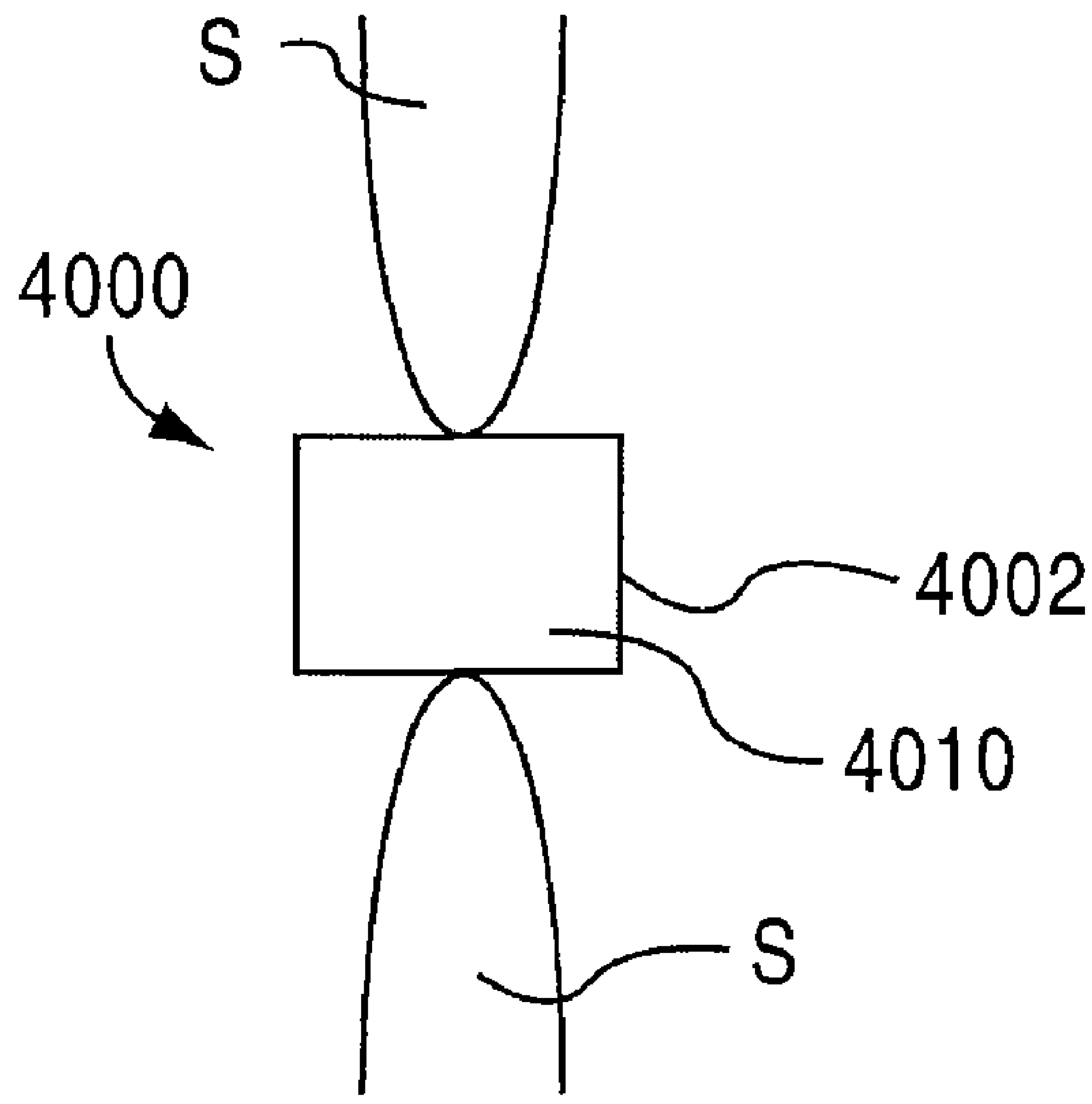


FIG.61B

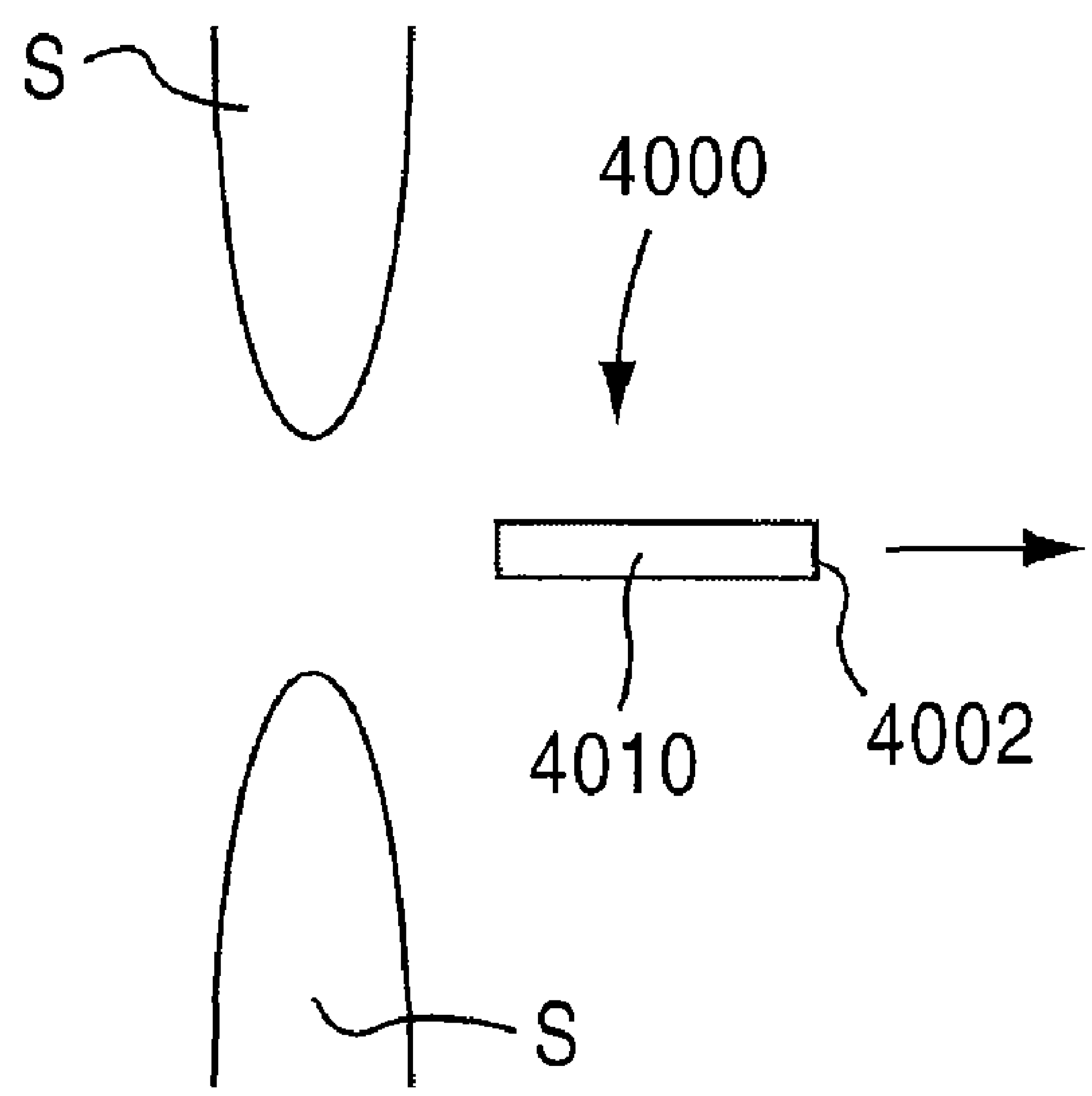


FIG.61C

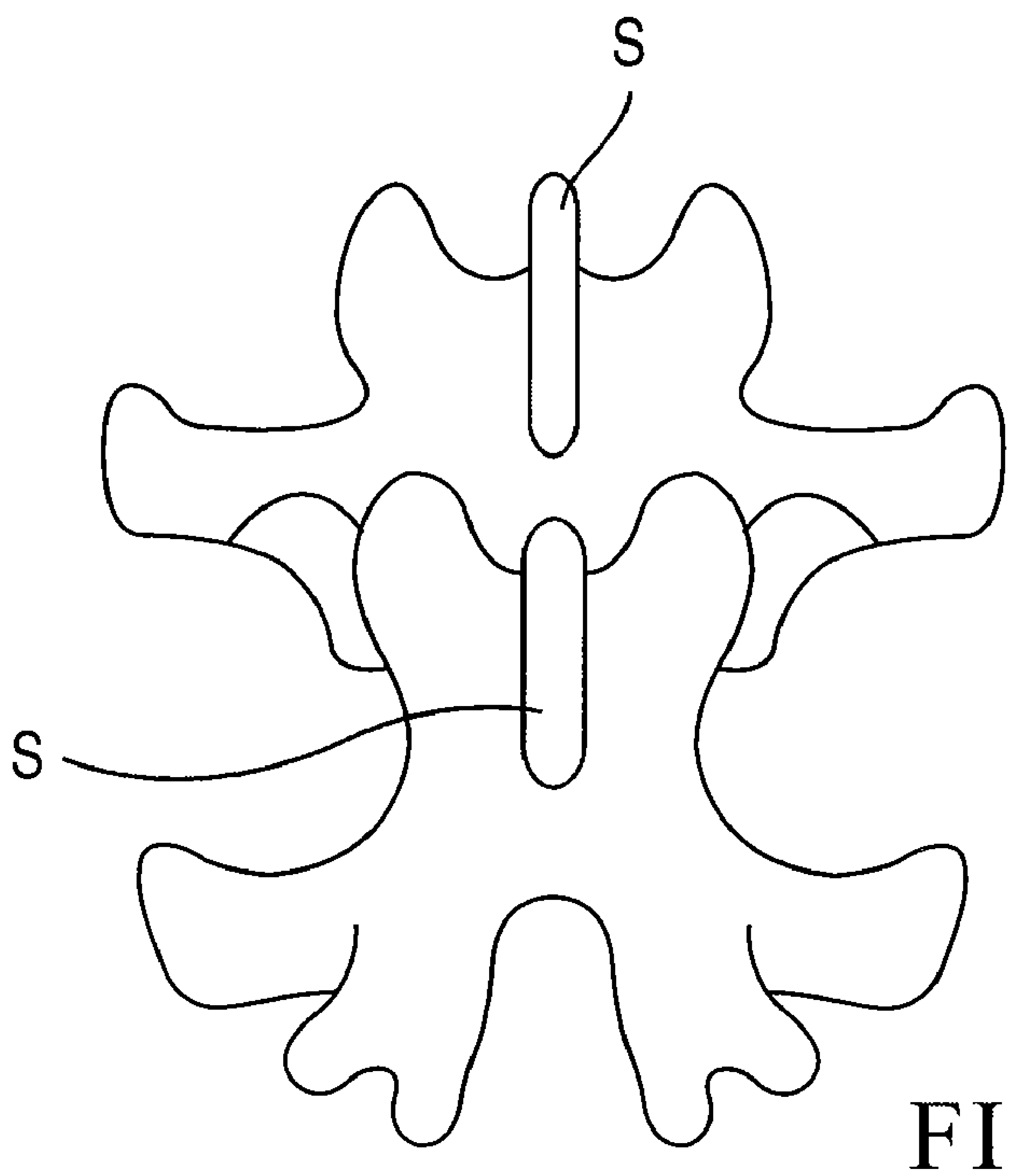


FIG.62A

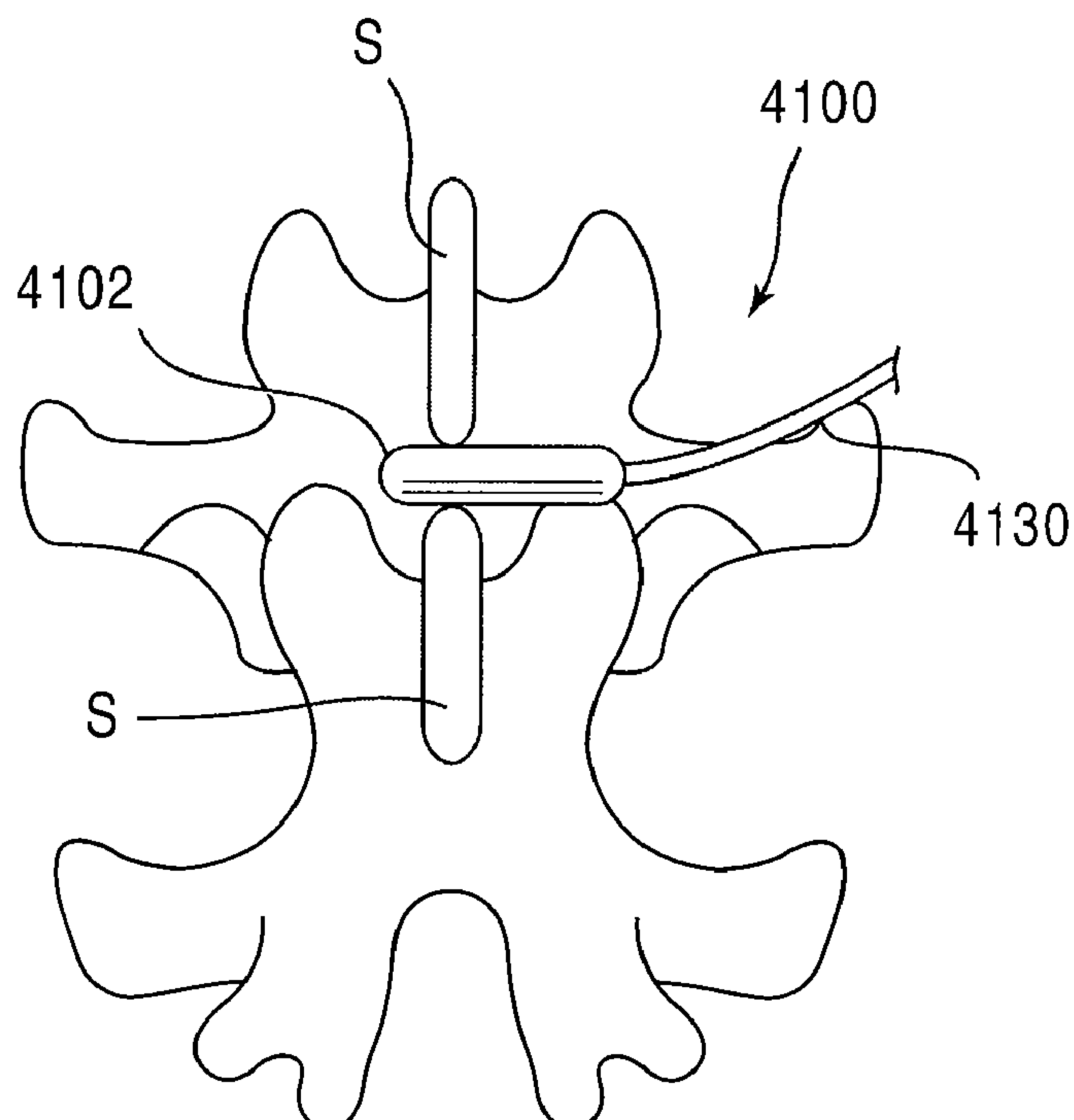


FIG.62B

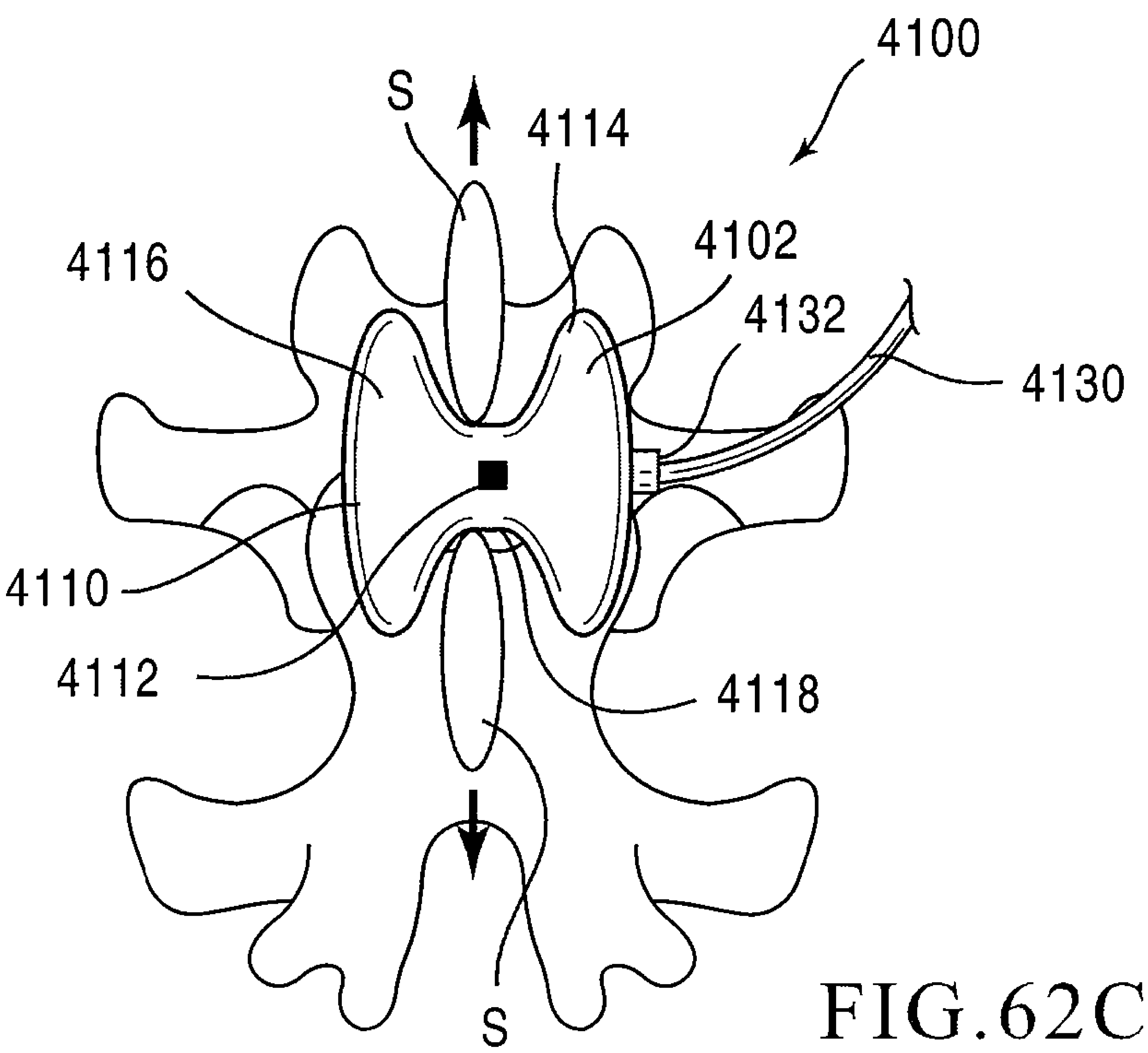


FIG.62C

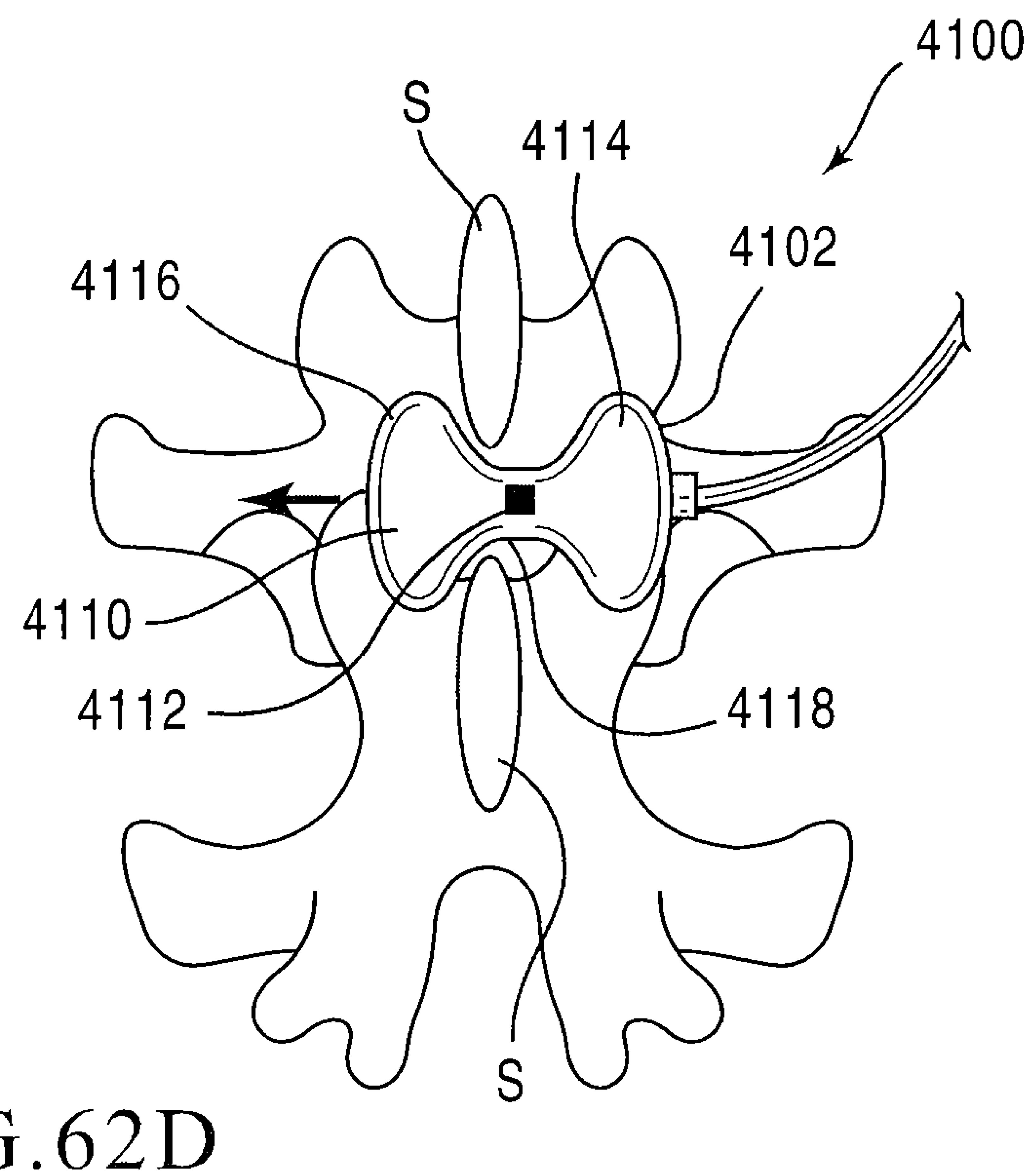


FIG.62D

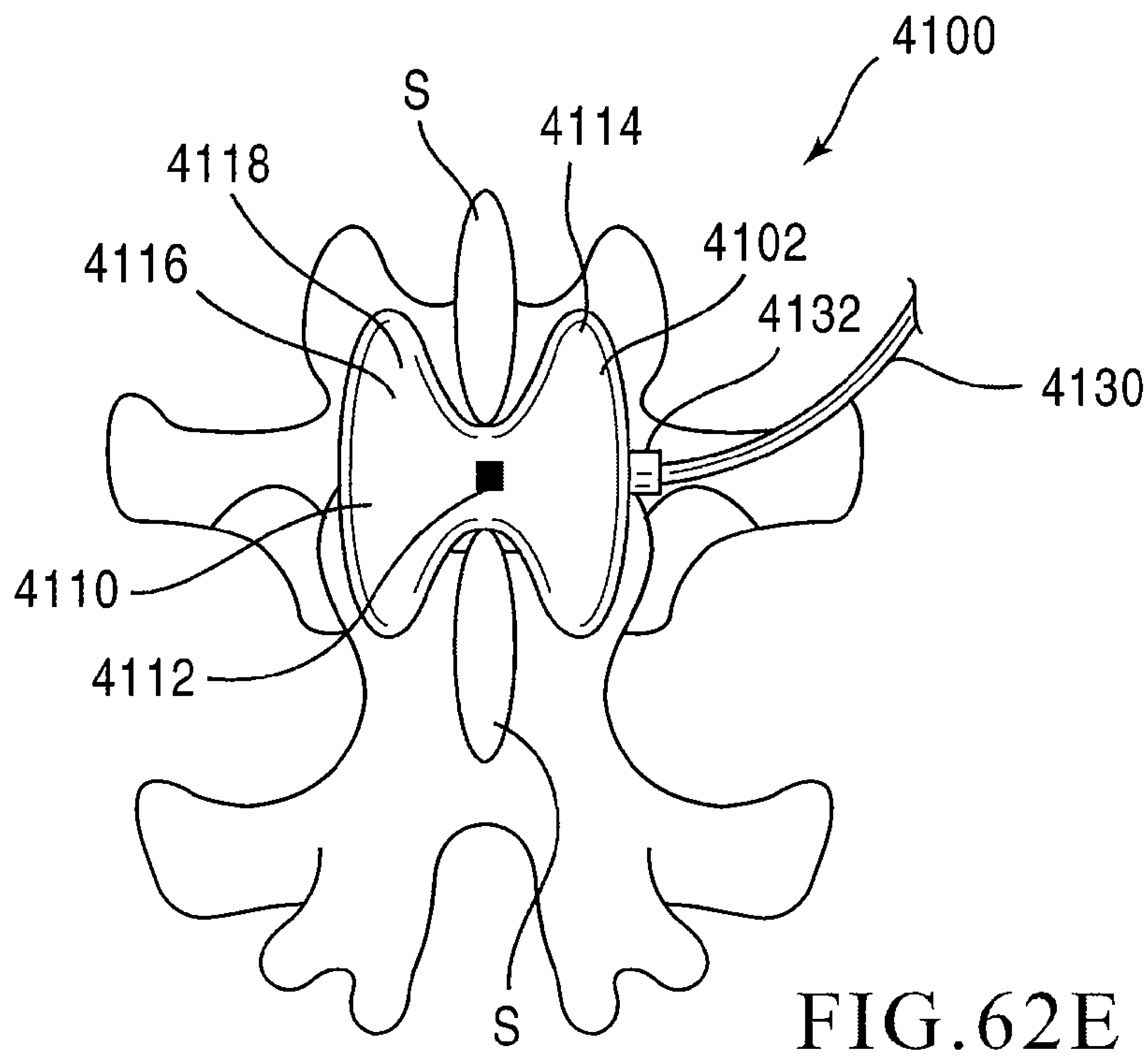


FIG.62E

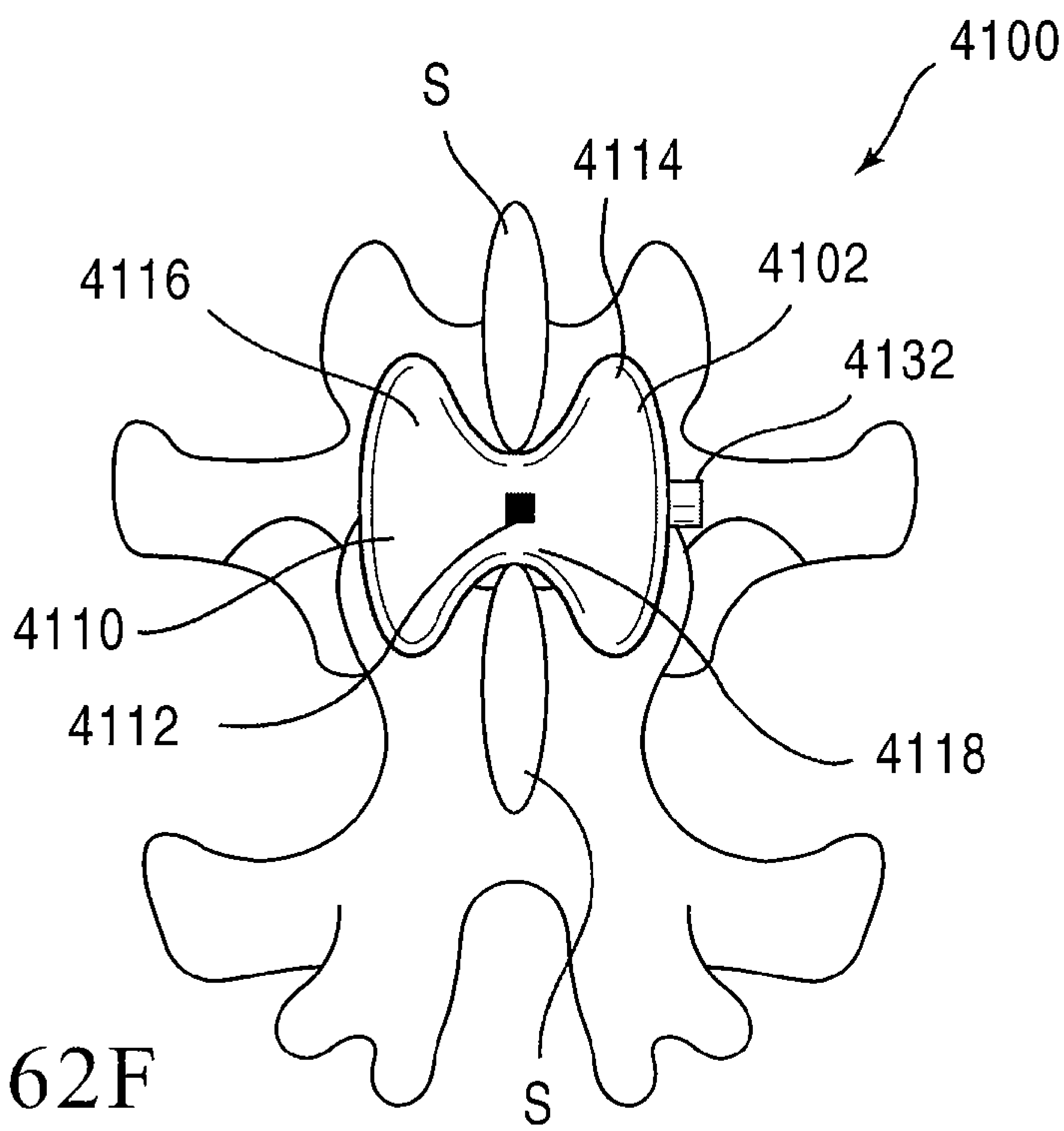


FIG.62F

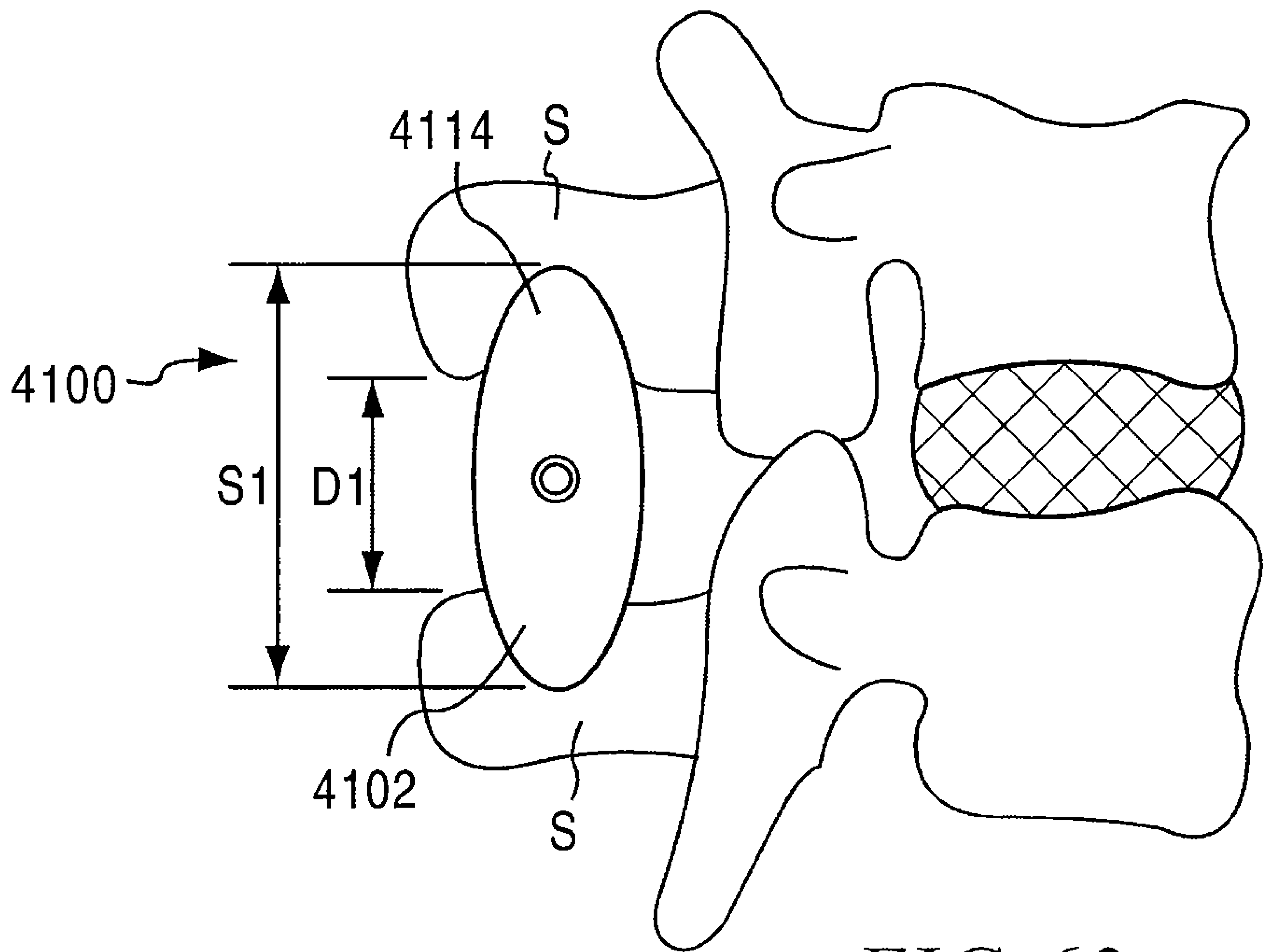

4114
S
4100
S1
D1
4102
S

FIG.63

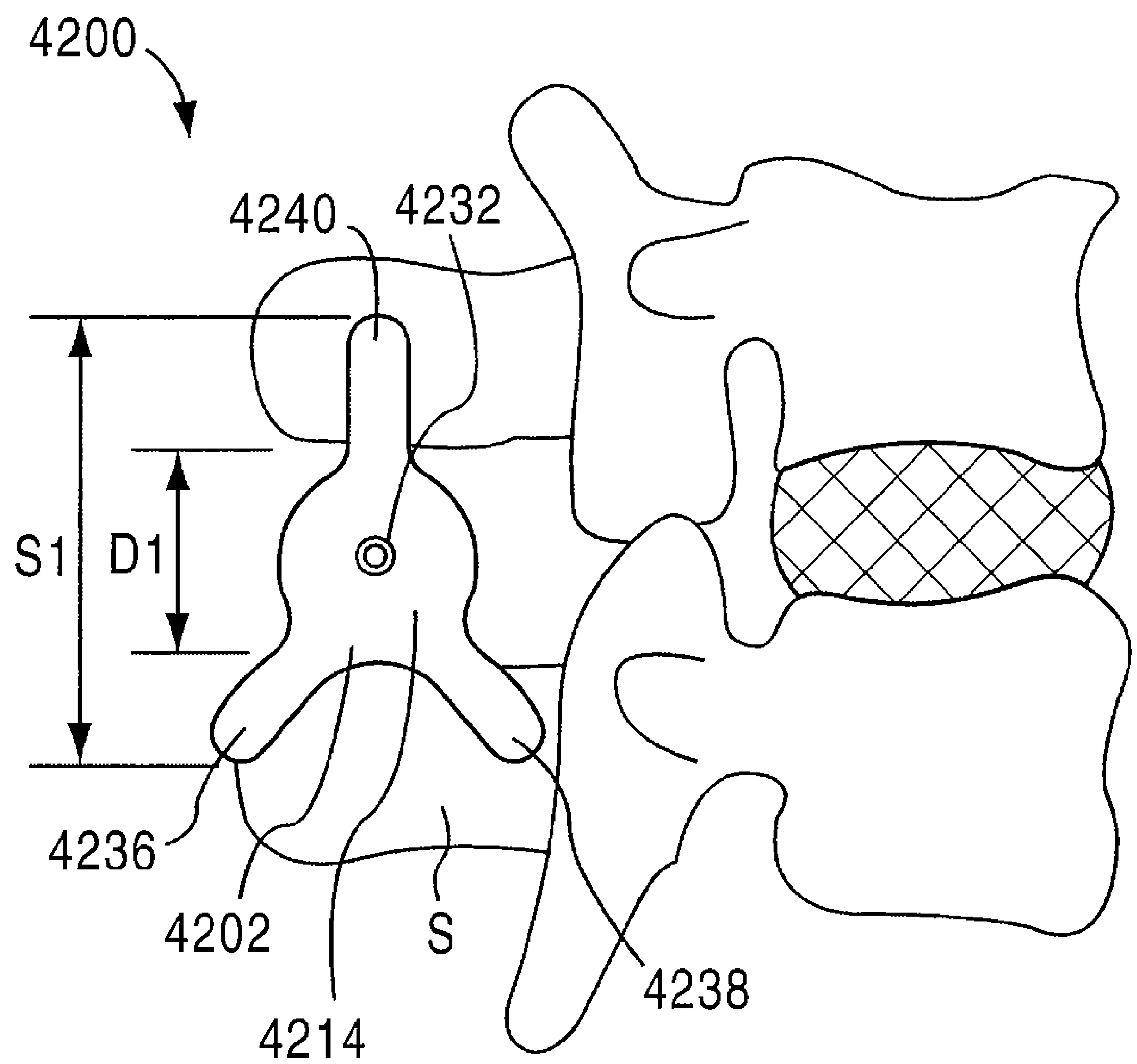

4200
4240
4232
S1
D1
4236
4202
S
4214
4238

FIG.64

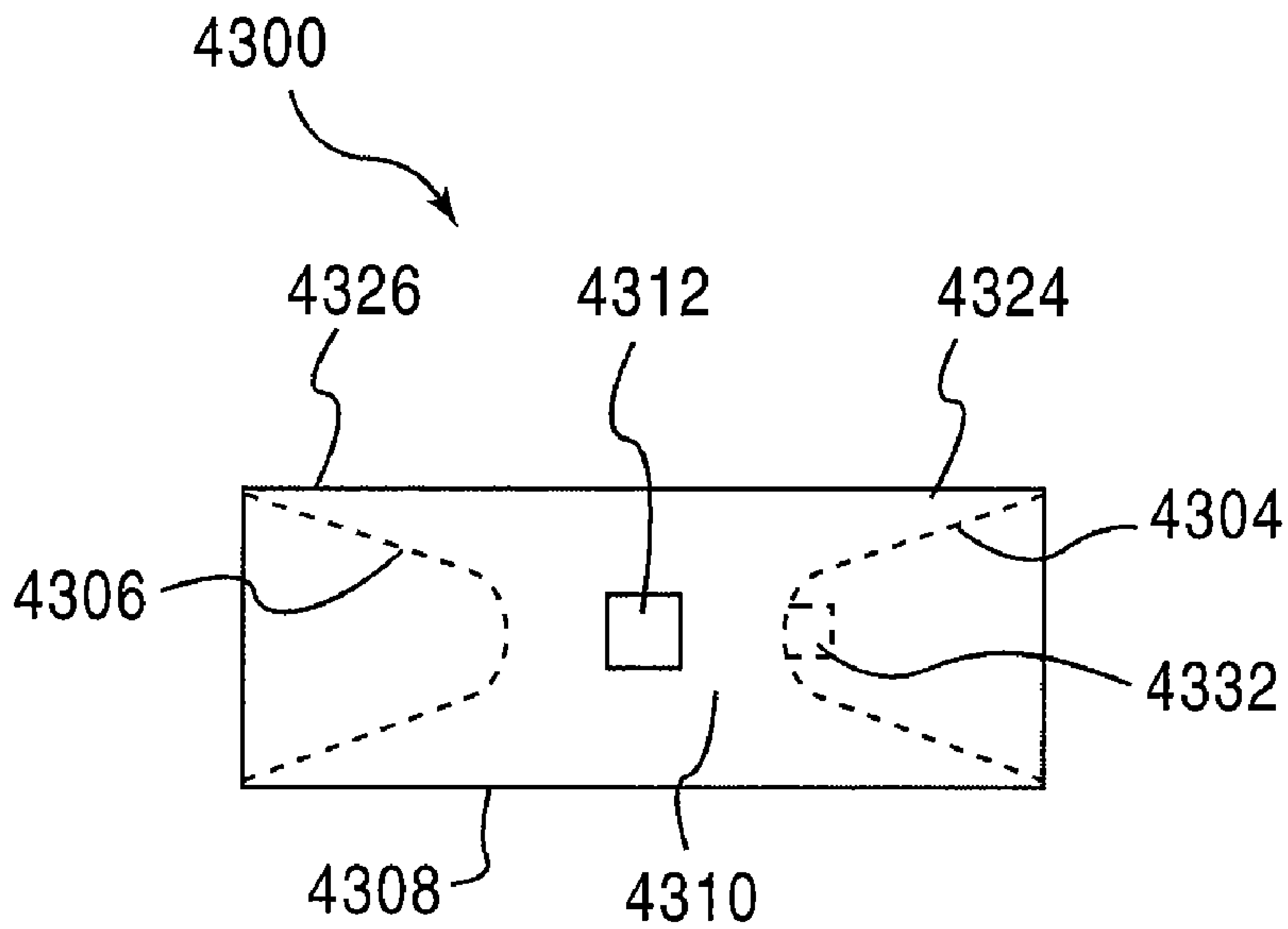


FIG.65A

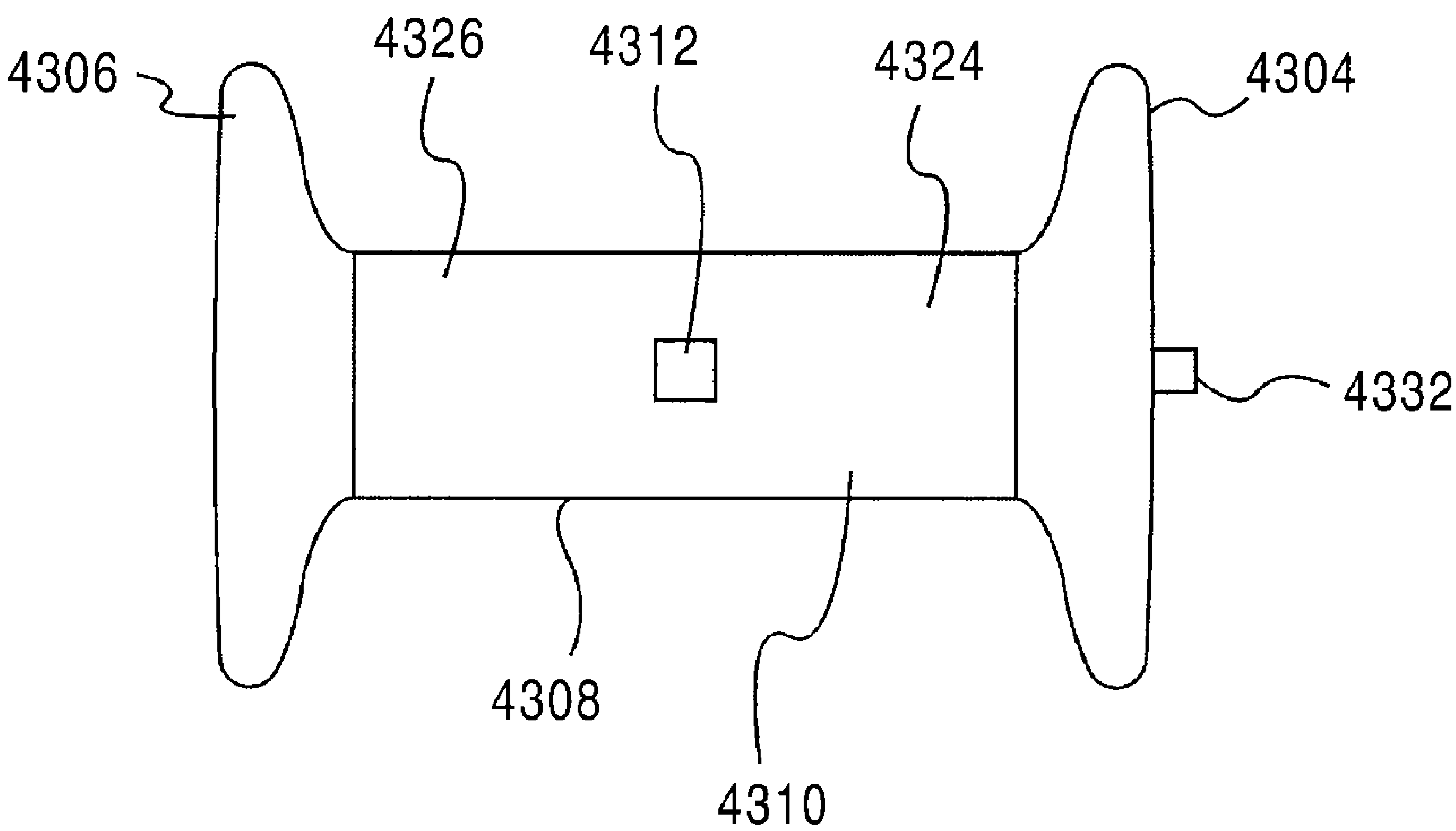


FIG.65B

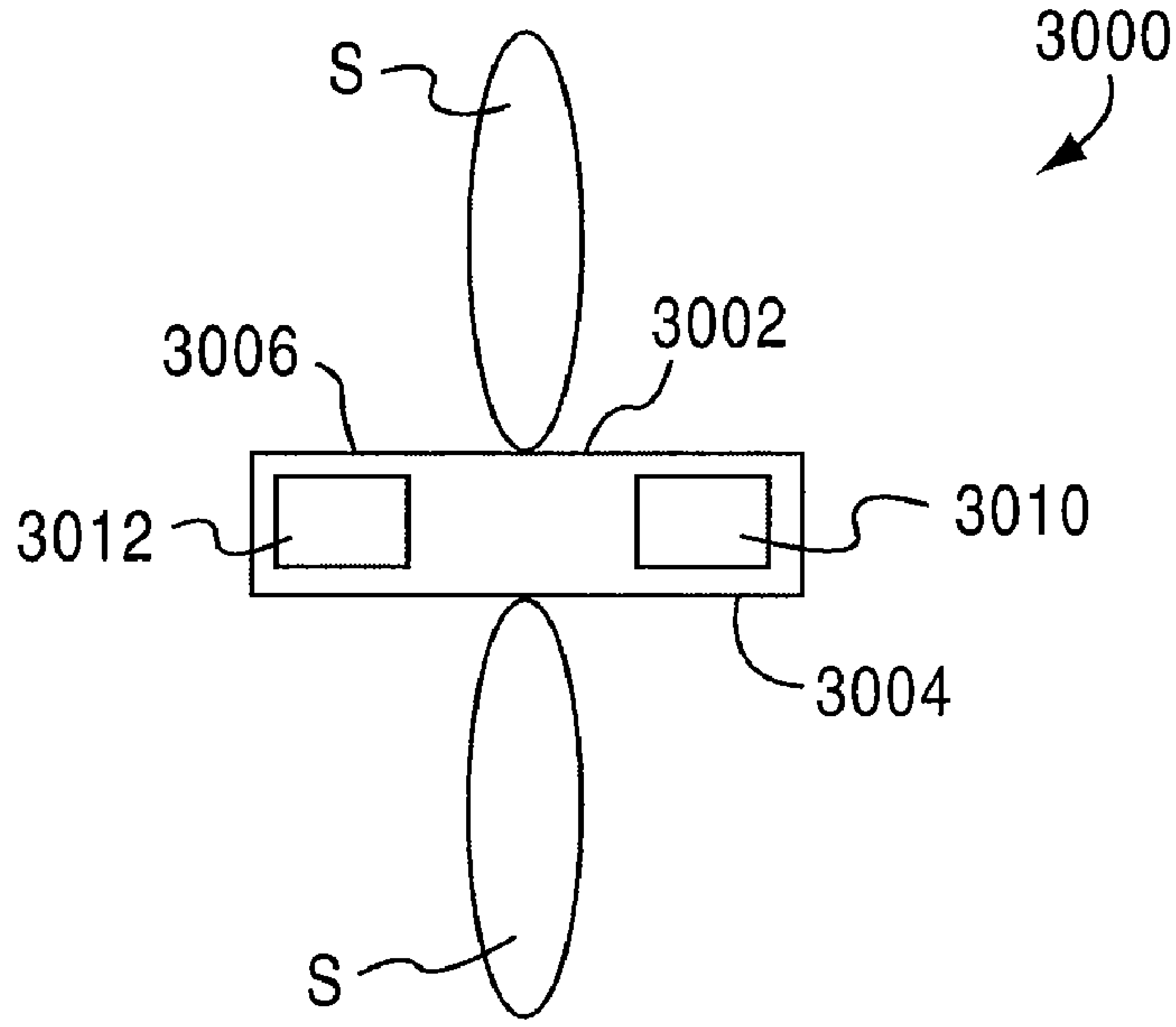


FIG.66A

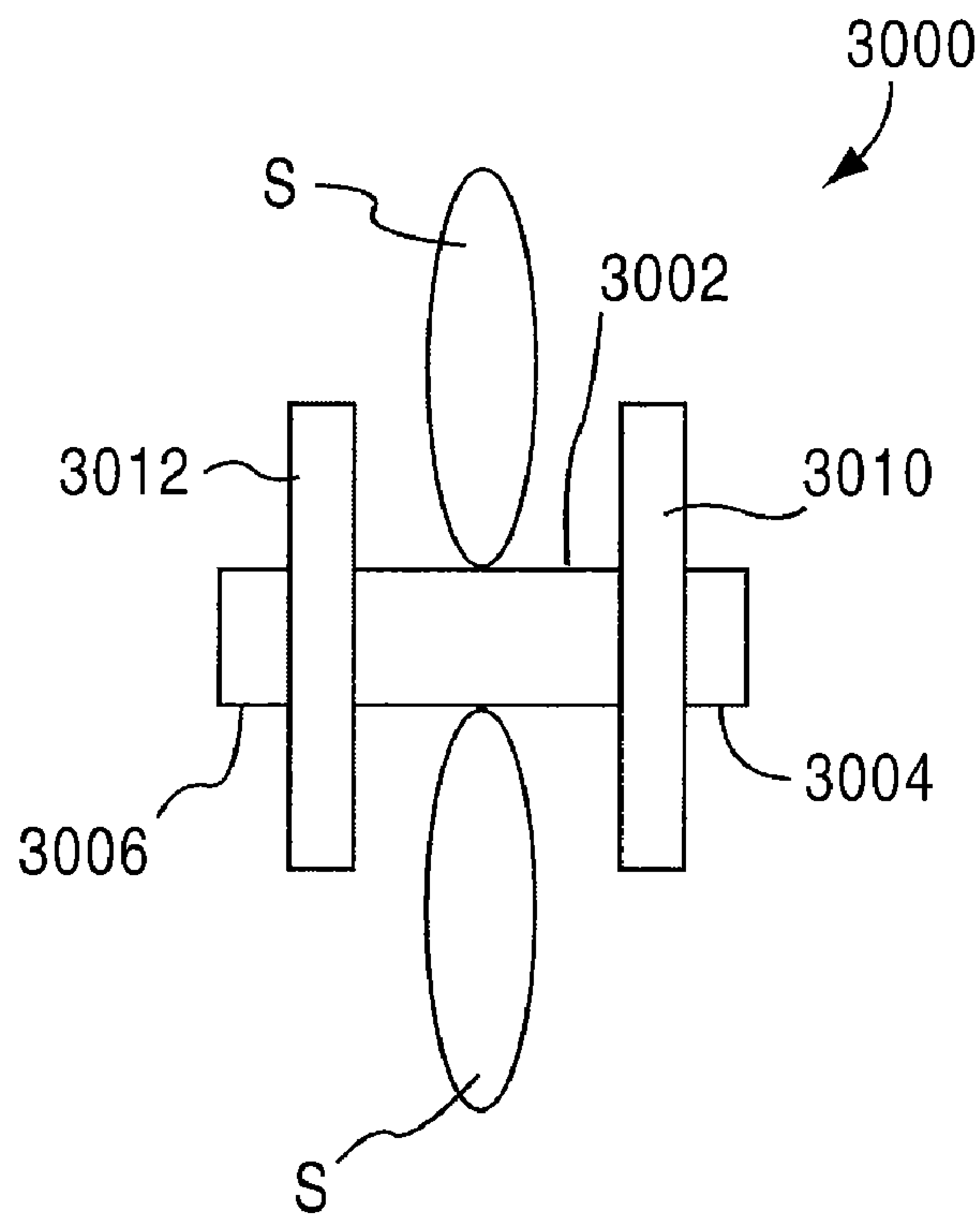


FIG.66B

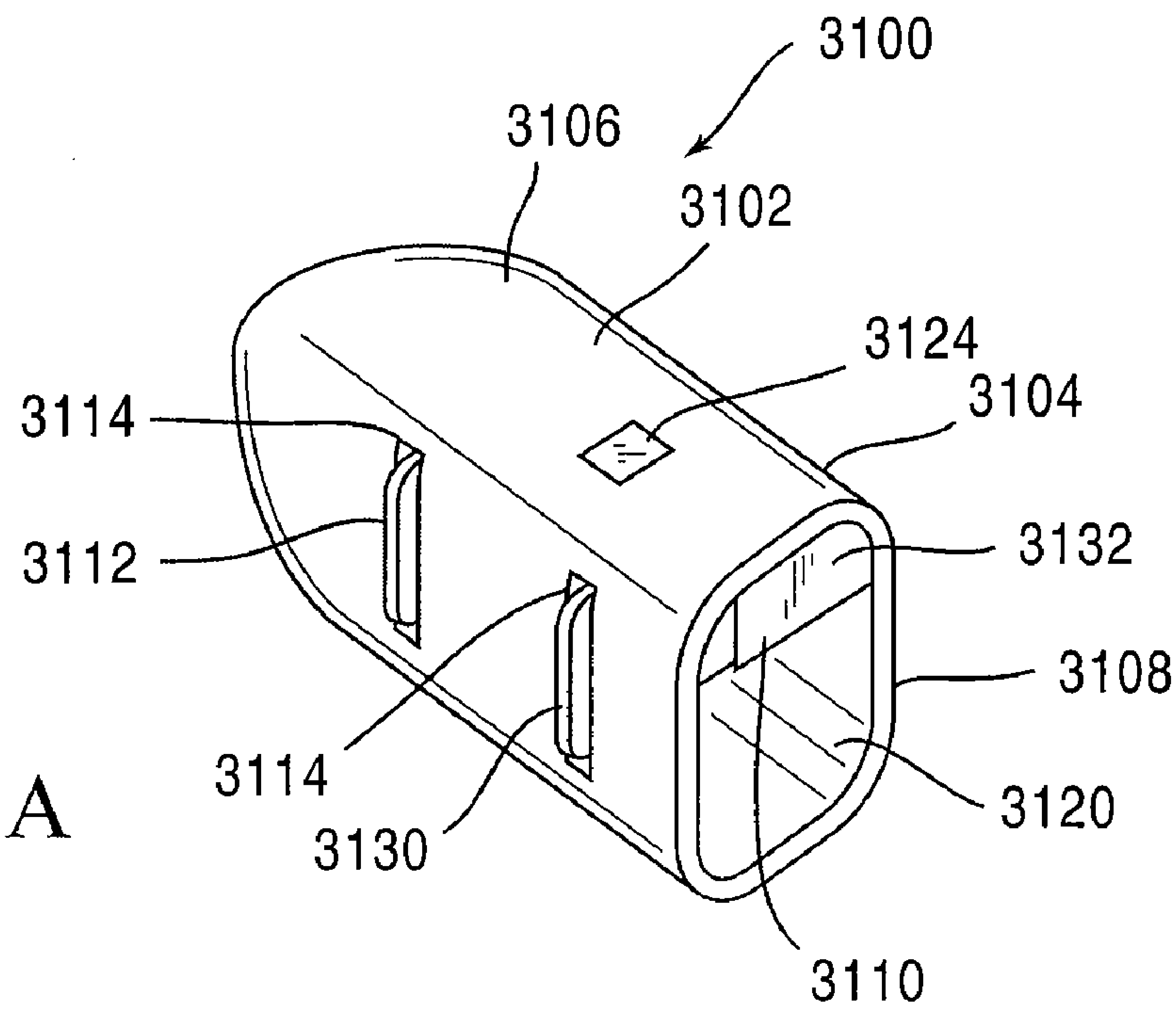


FIG.67A

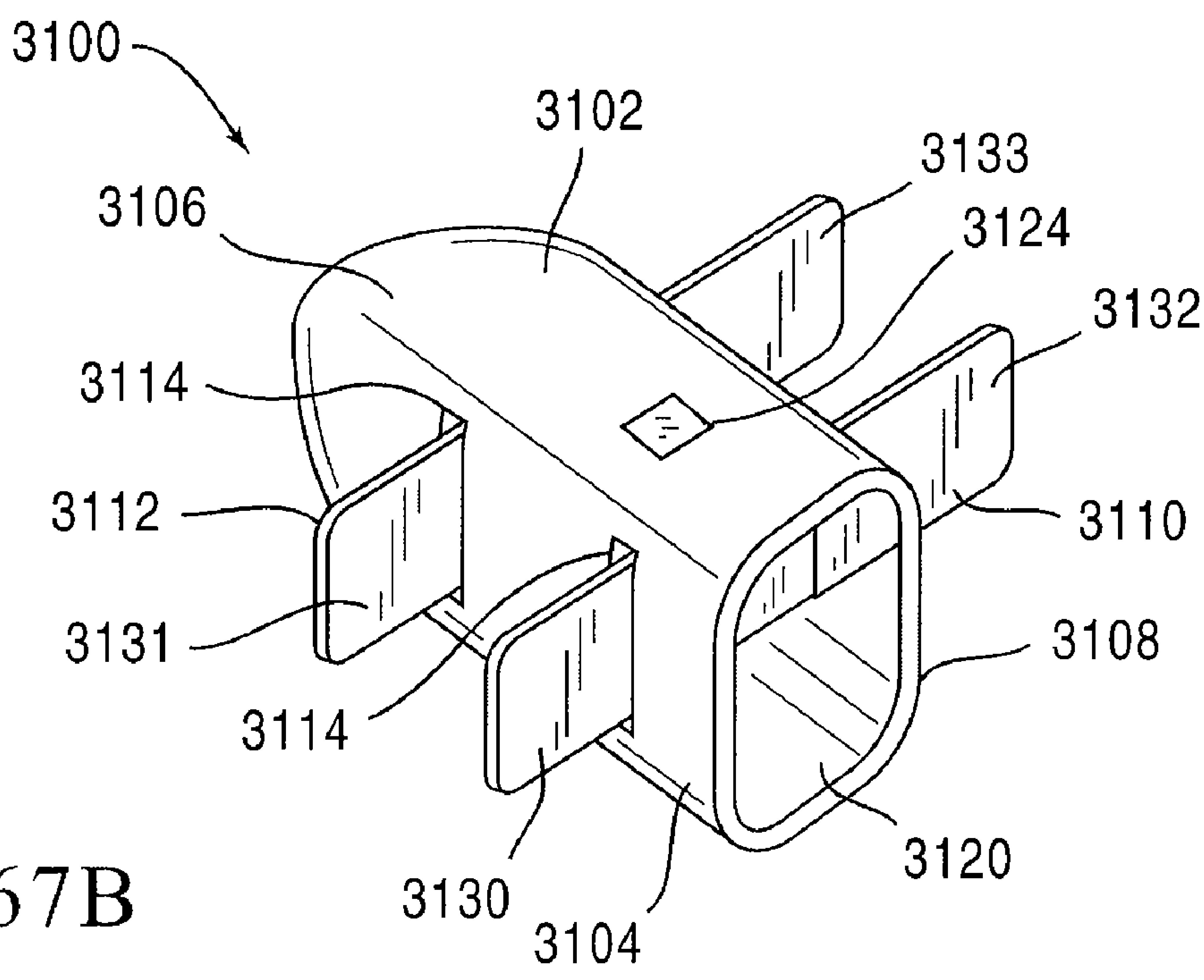


FIG.67B

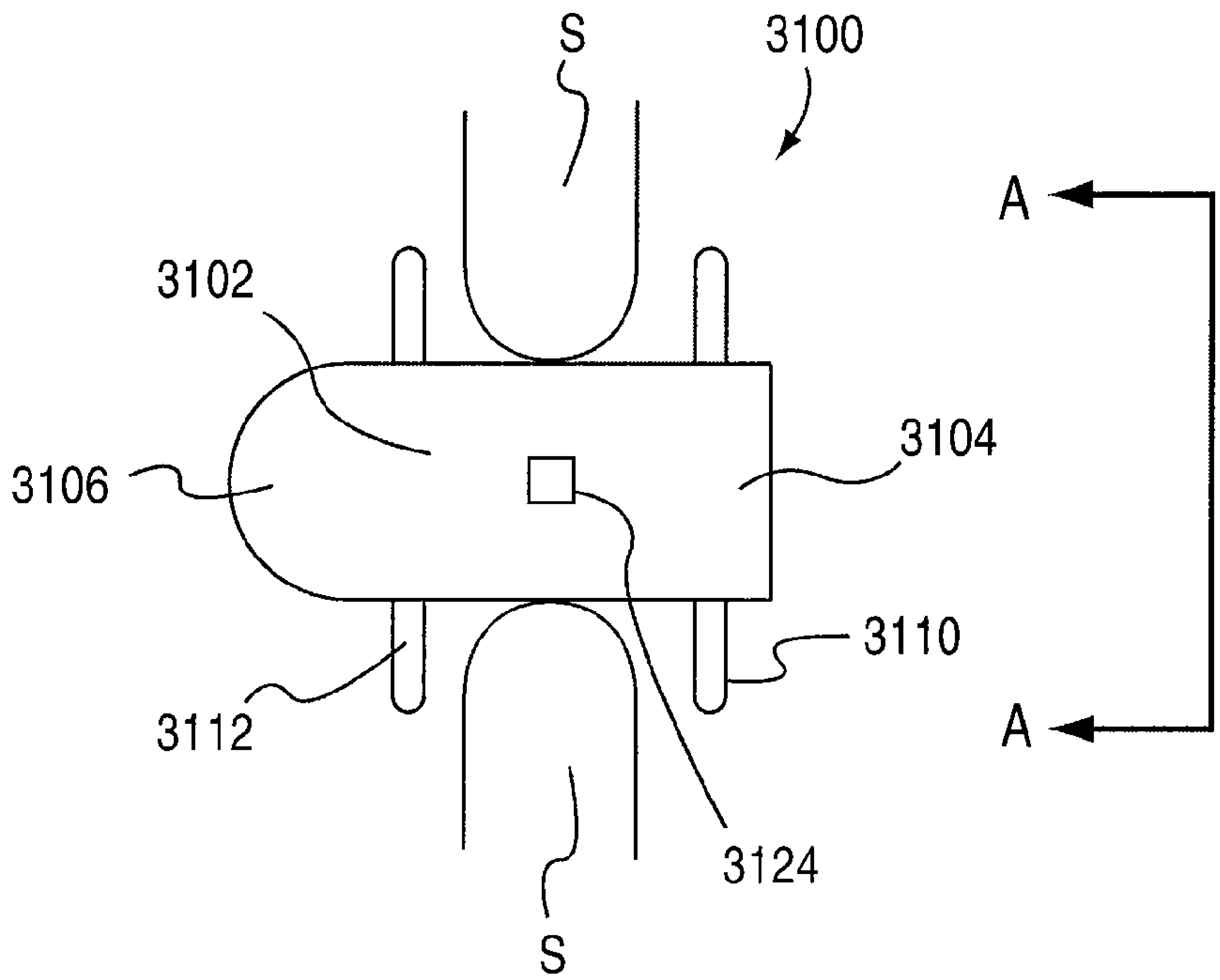

S
3100
A
3102
3104
3106
3110
3112
3124
S
A

FIG.68

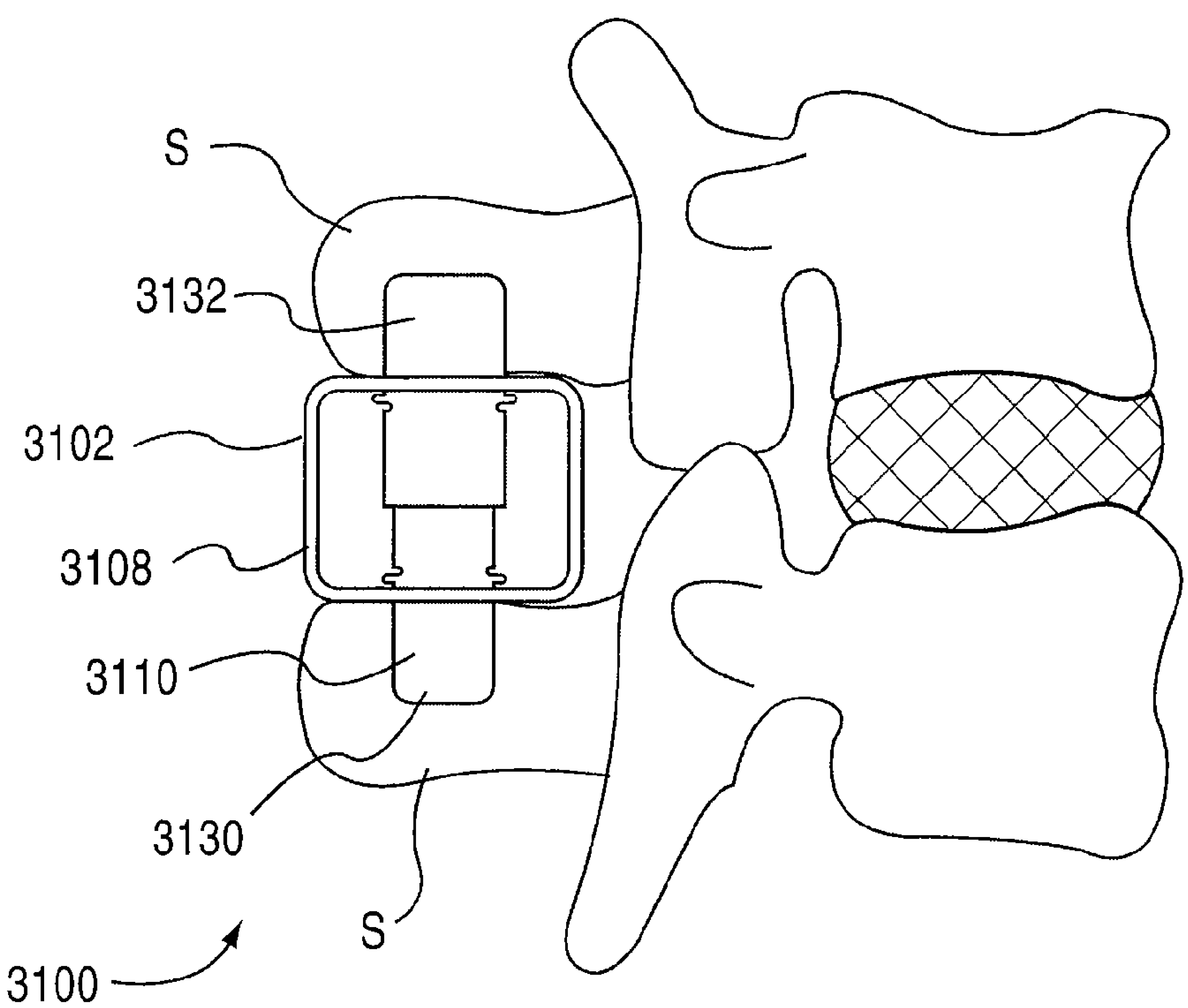

S
3132
3102
3108
3110
3130
S
3100

FIG.69

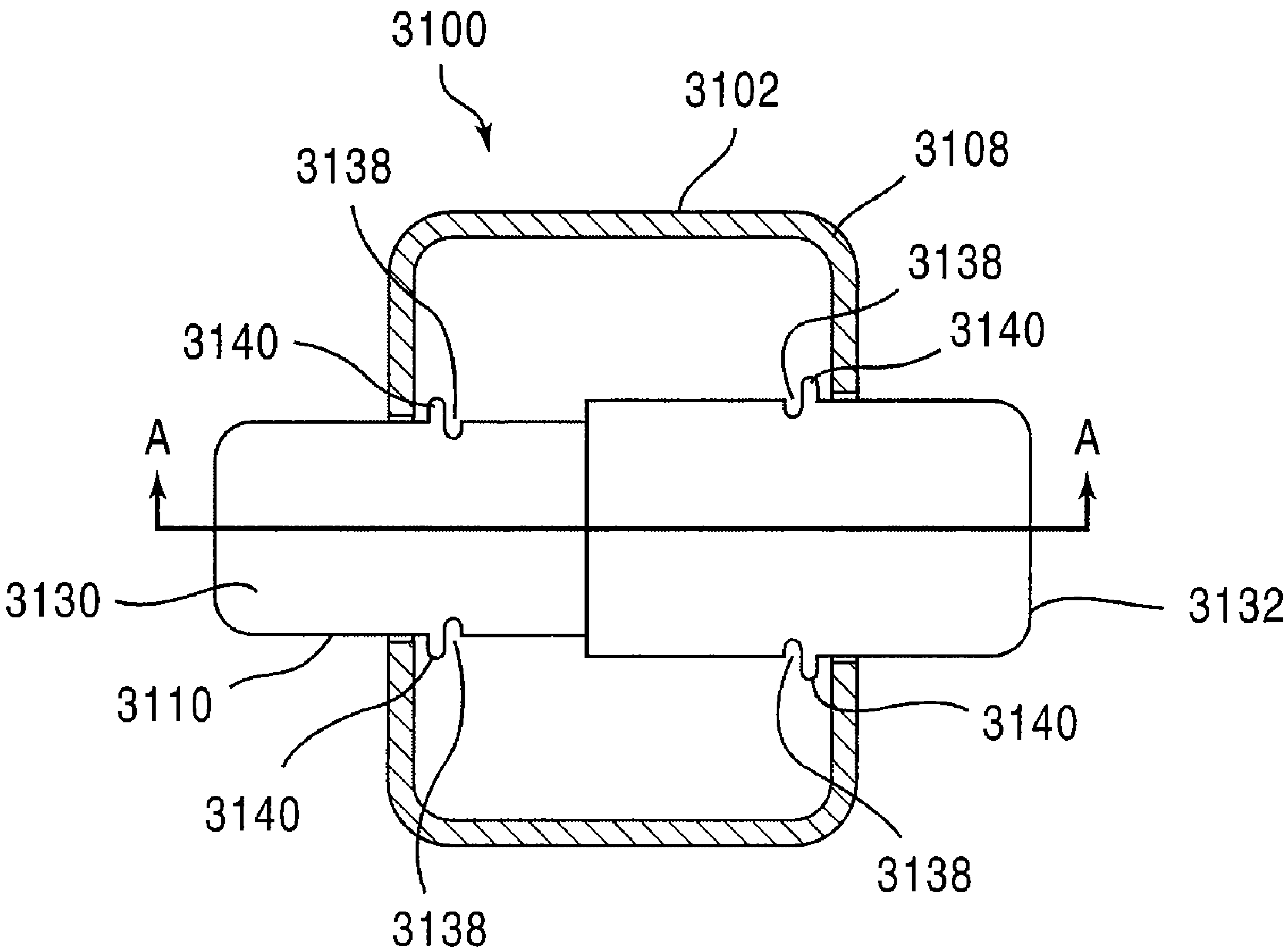

3100
3102
3108
3138
3138
3140
3140
A
A
3130
3132
3110
3140
3140
3138
3138

FIG.70

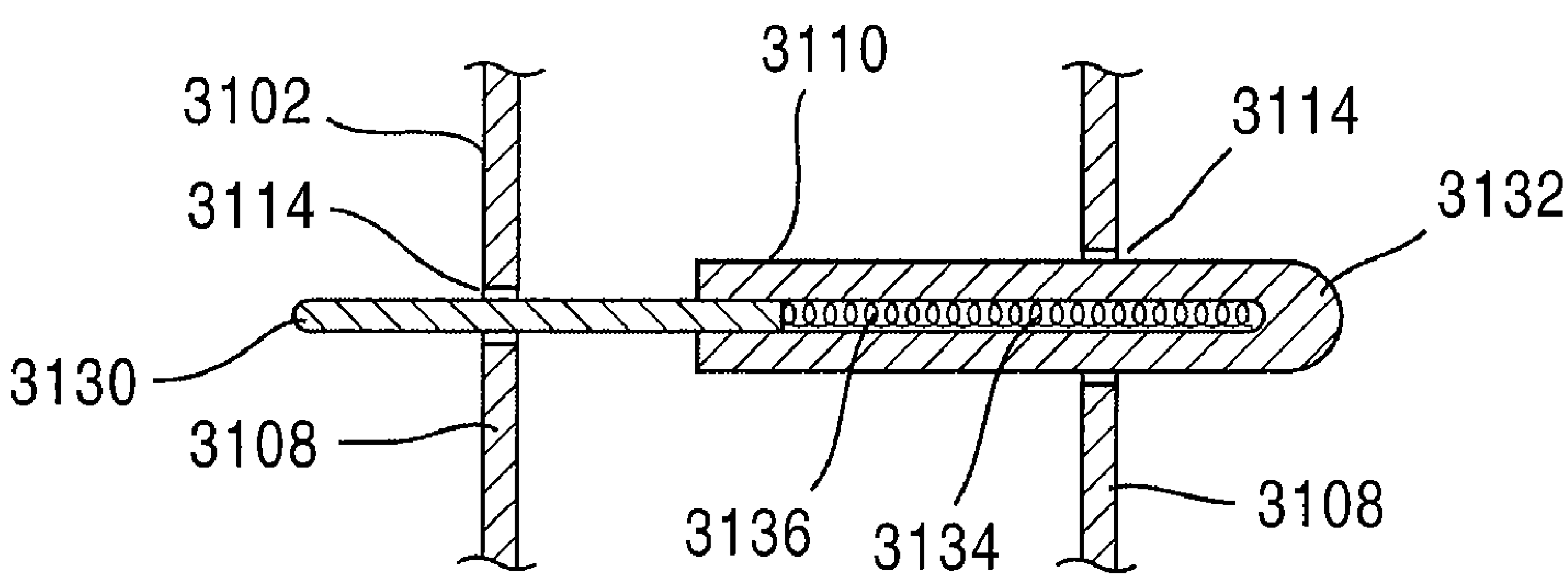

3110
3102
3114
3114
3132
3130
3108
3136
3134
3108

FIG.71

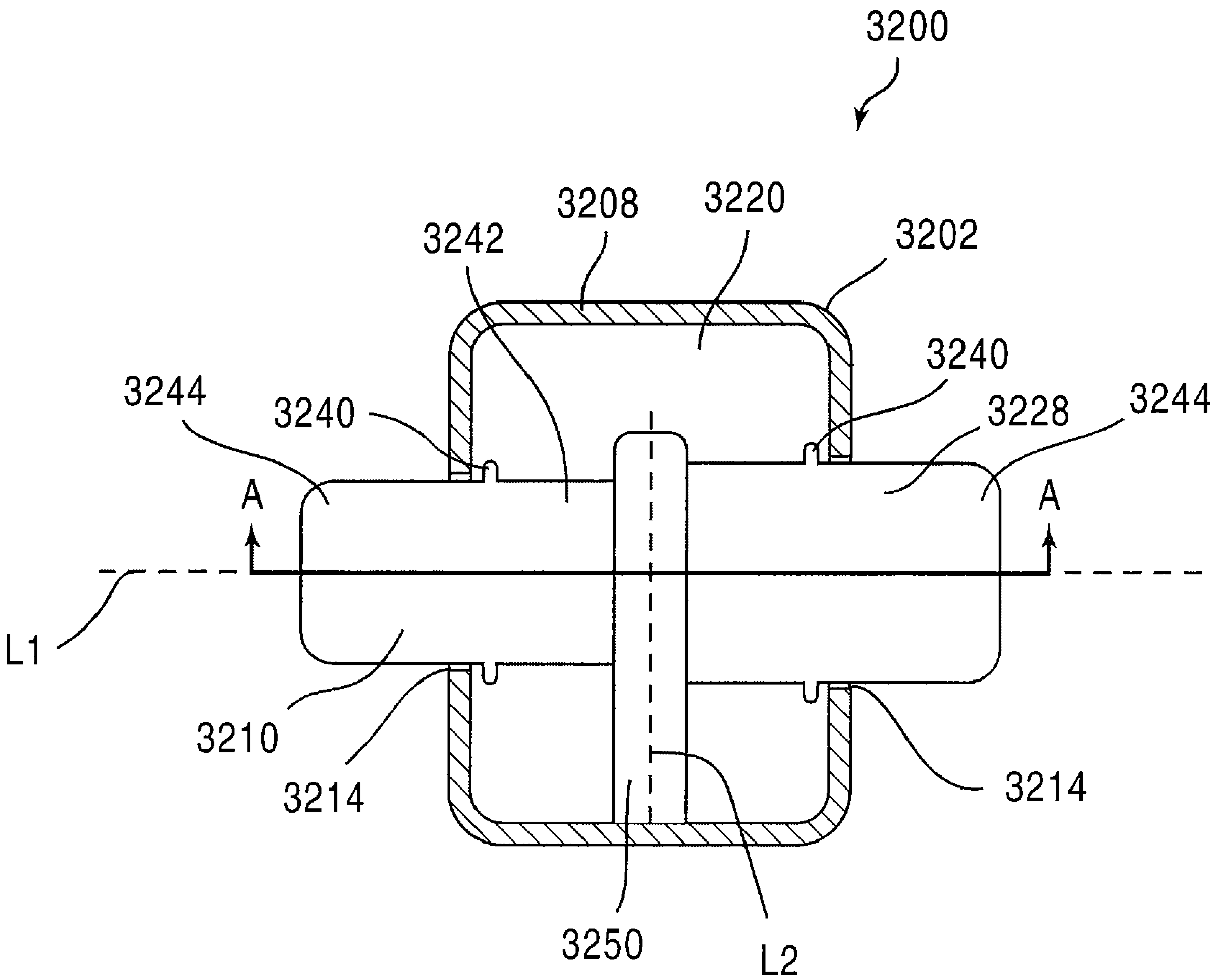

3200
3208
3220
3242
3202
3240
3244
3240
3228
3244
A
A
L1
3210
3214
3214
3250
L2

FIG.72

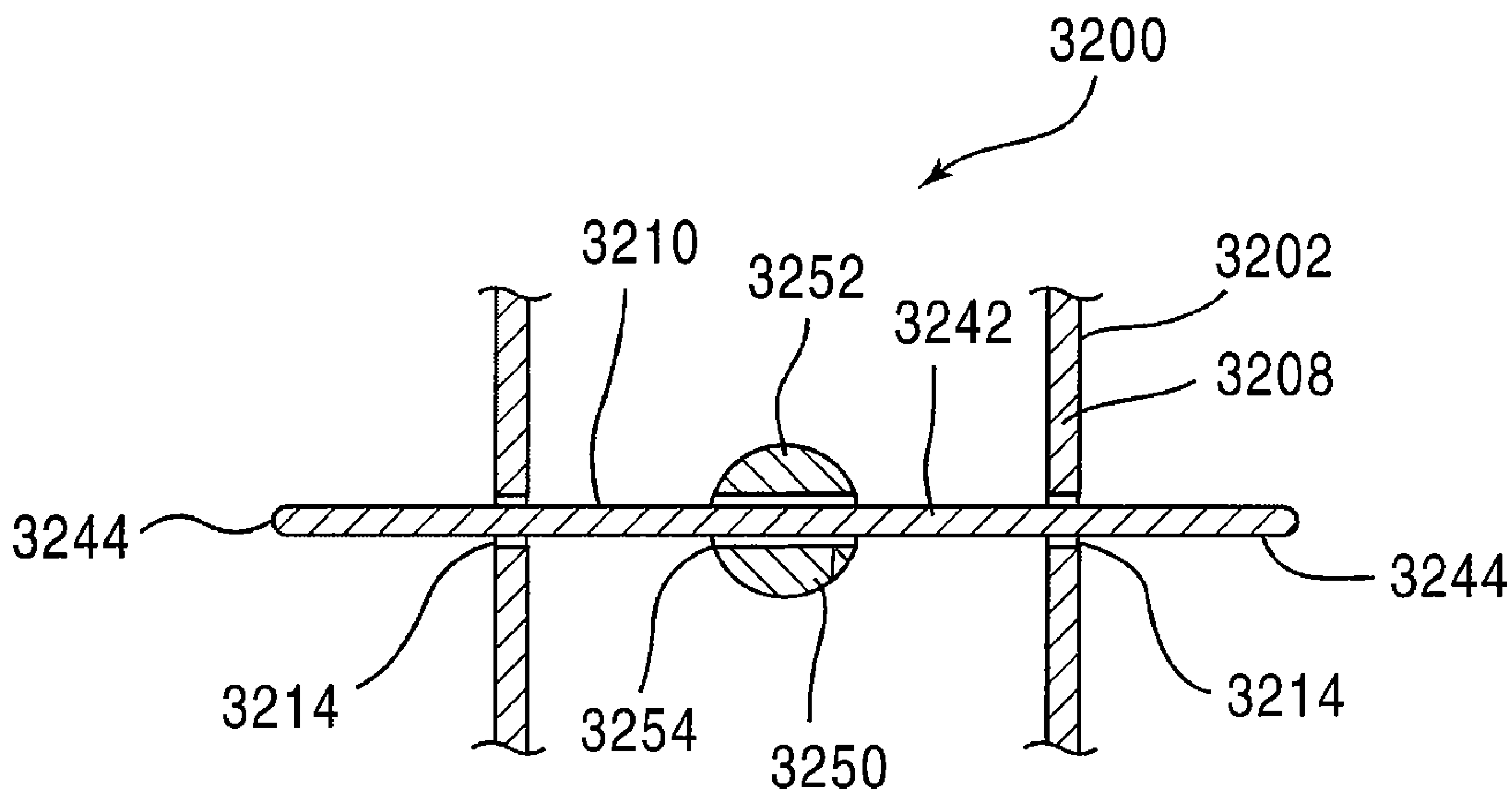


FIG.73A

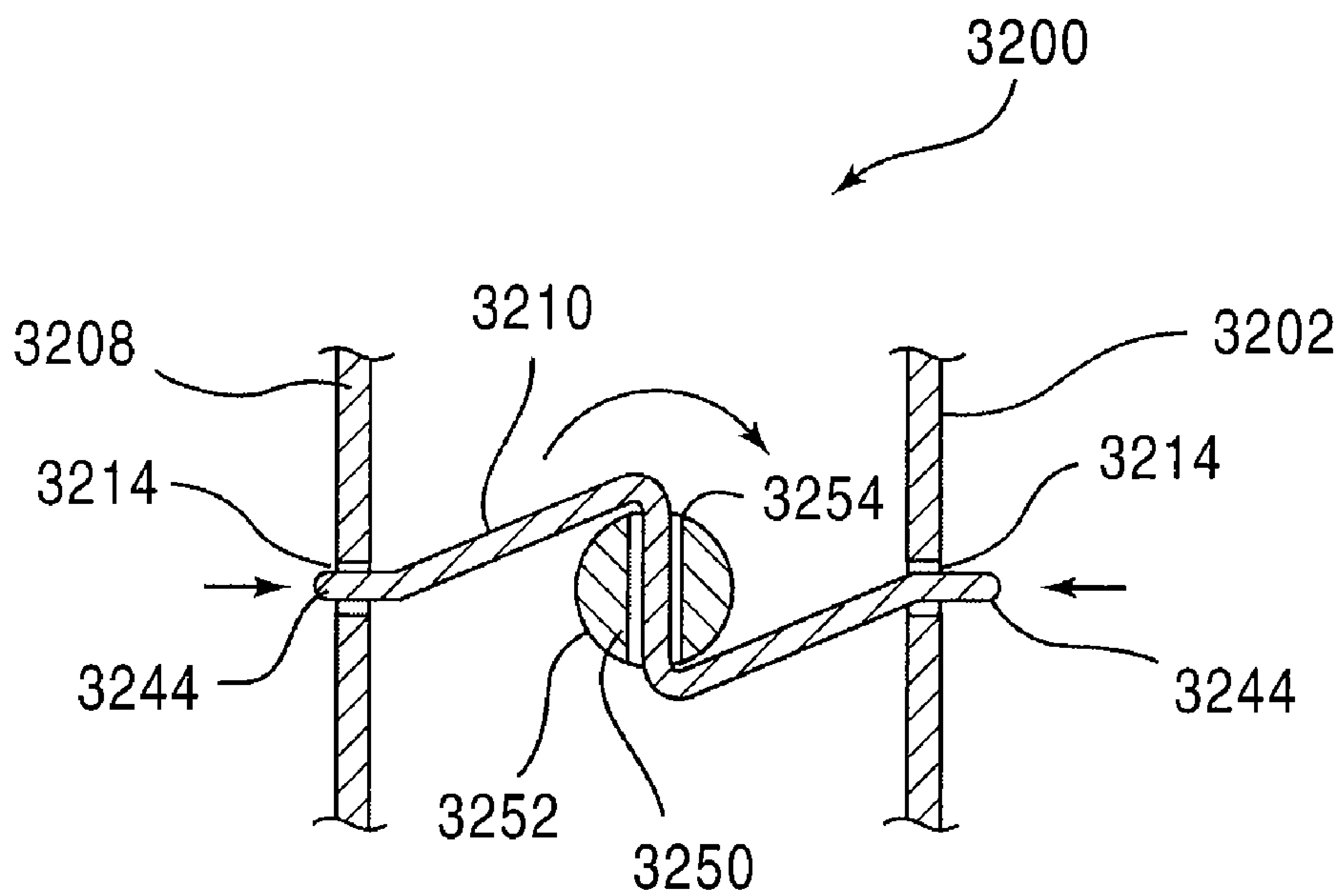


FIG.73B

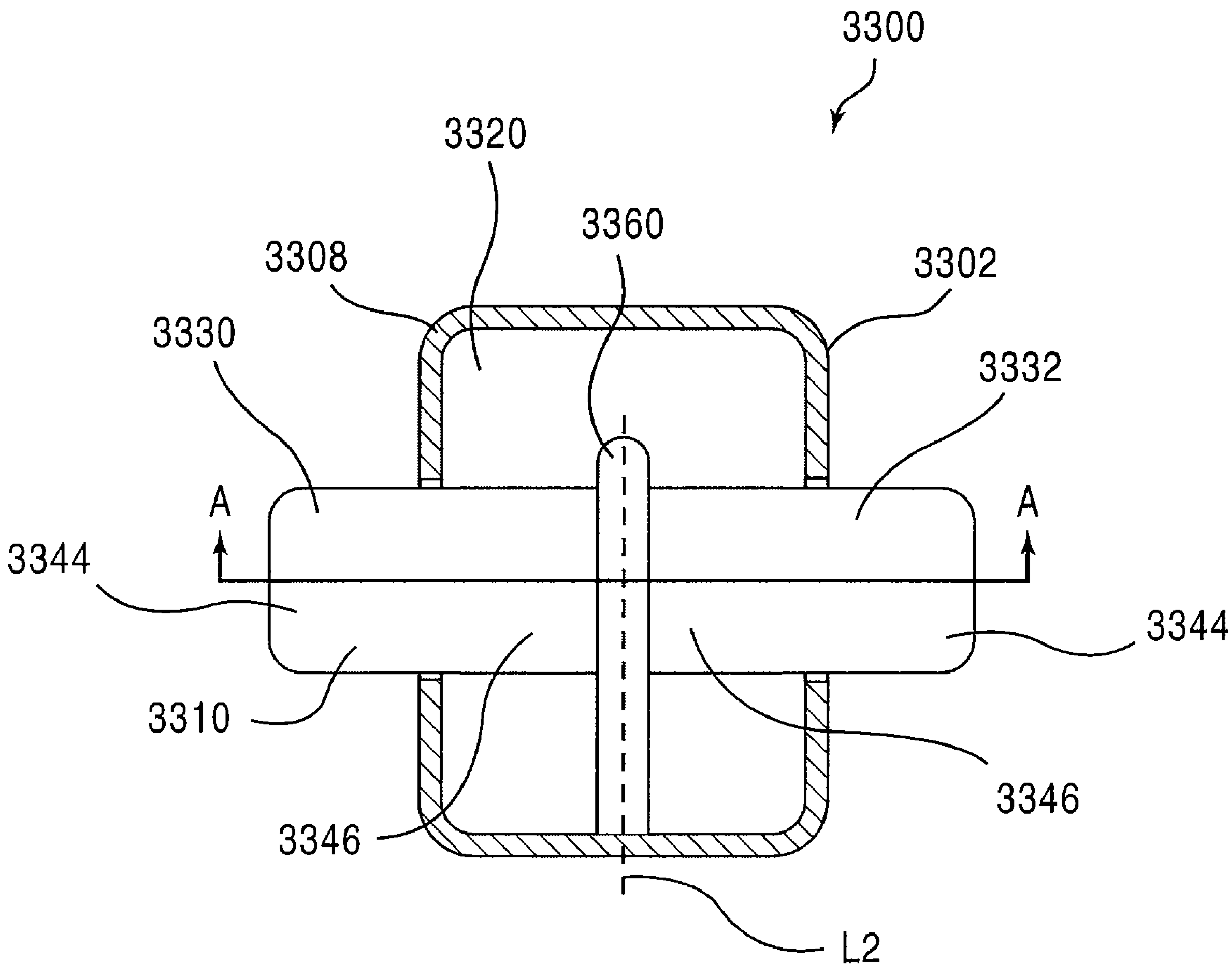

3300
3320
3360
3308
3302
3330
3332
A
A
3344
3344
3310
3346
3346
L2

FIG. 74

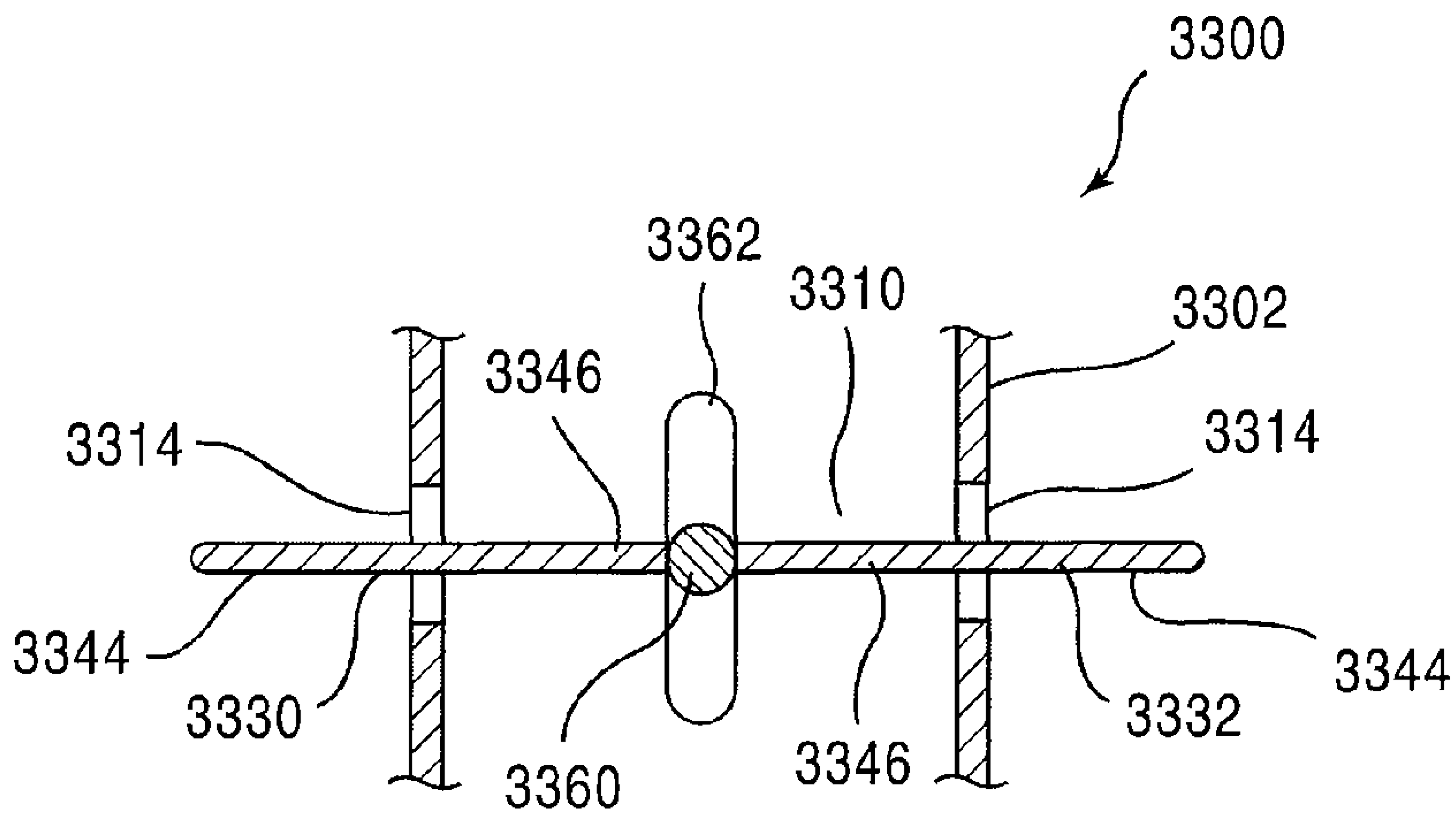


FIG.75A

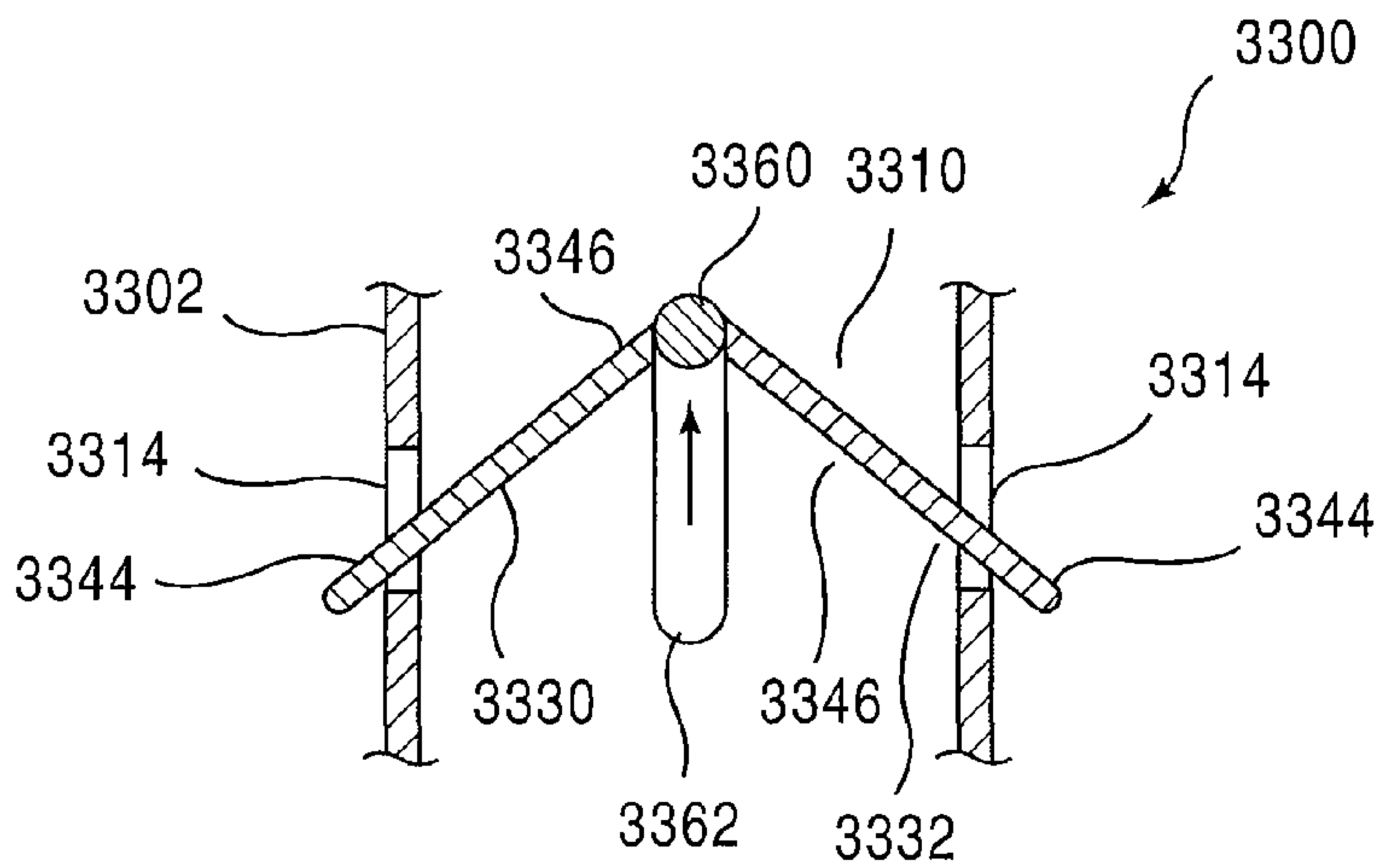


FIG.75B

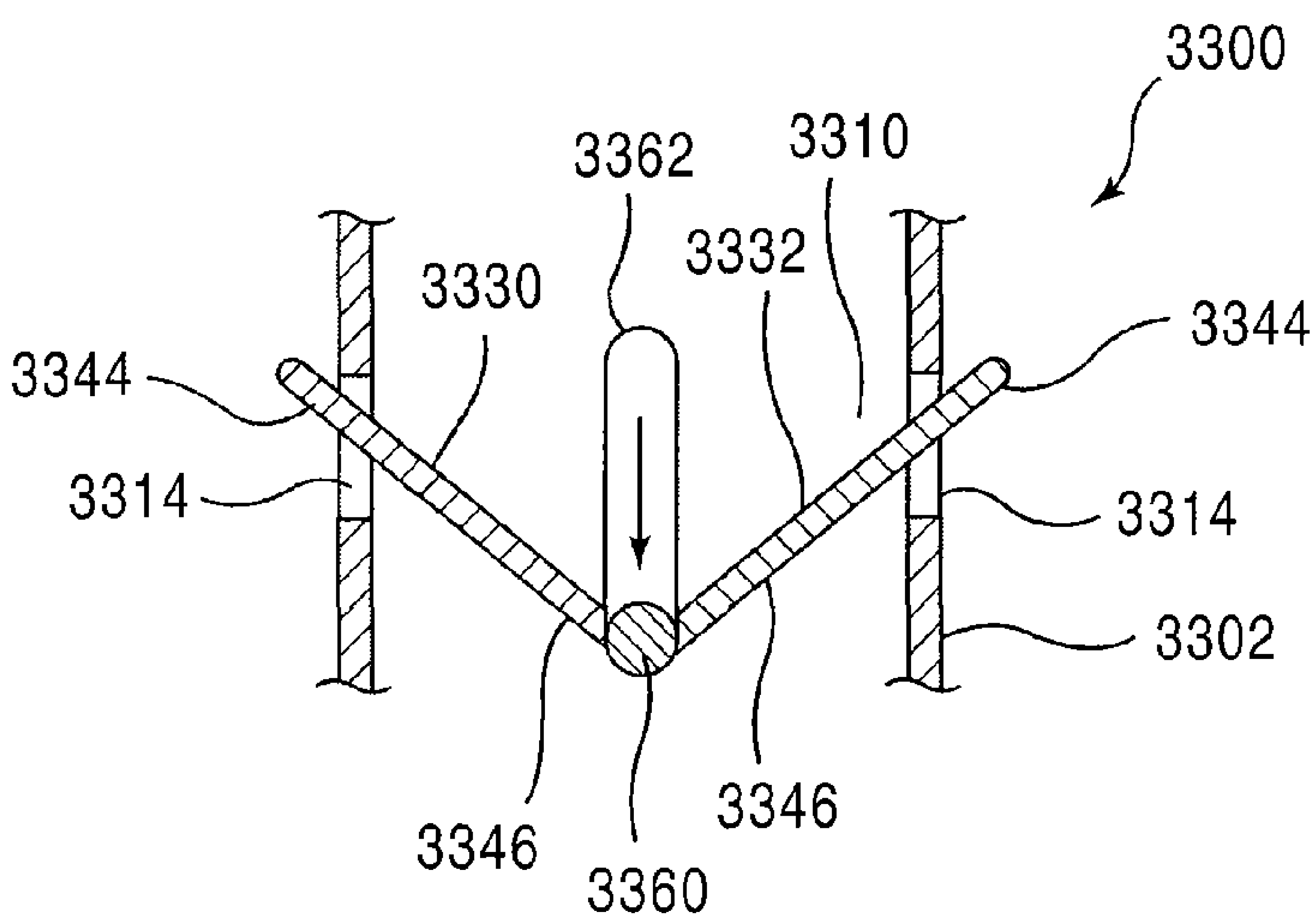


FIG.75C

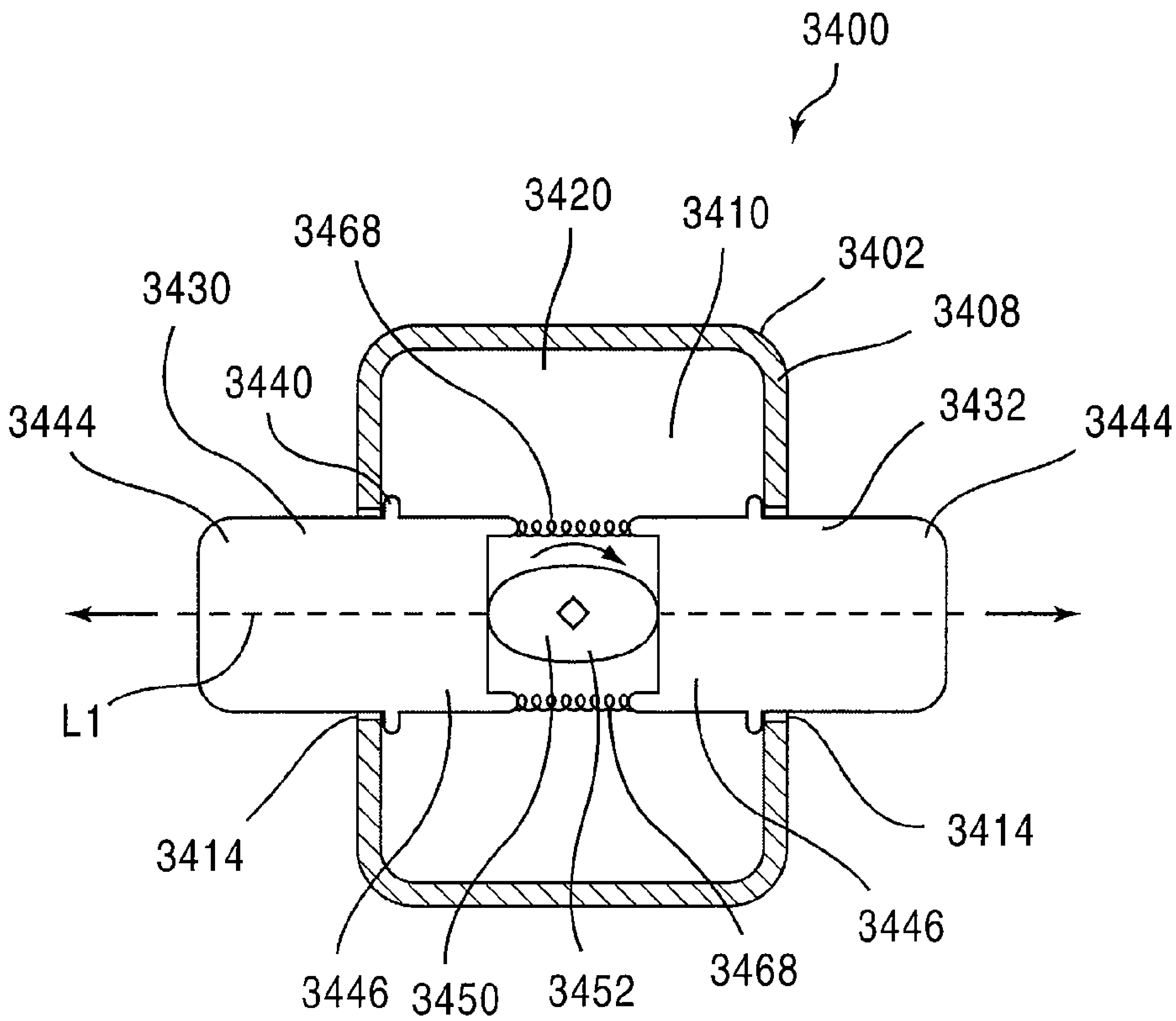


FIG.76A

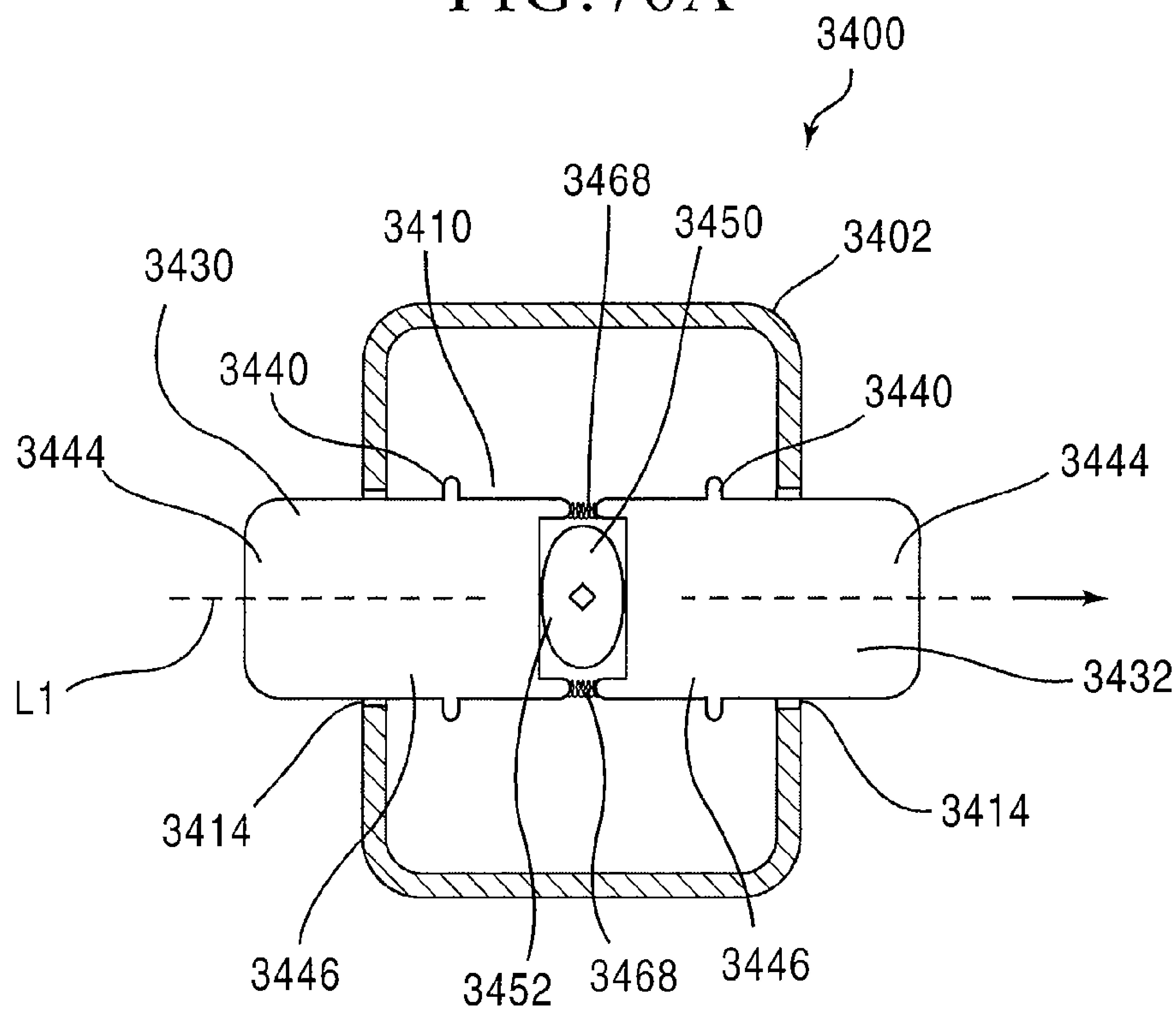


FIG.76B

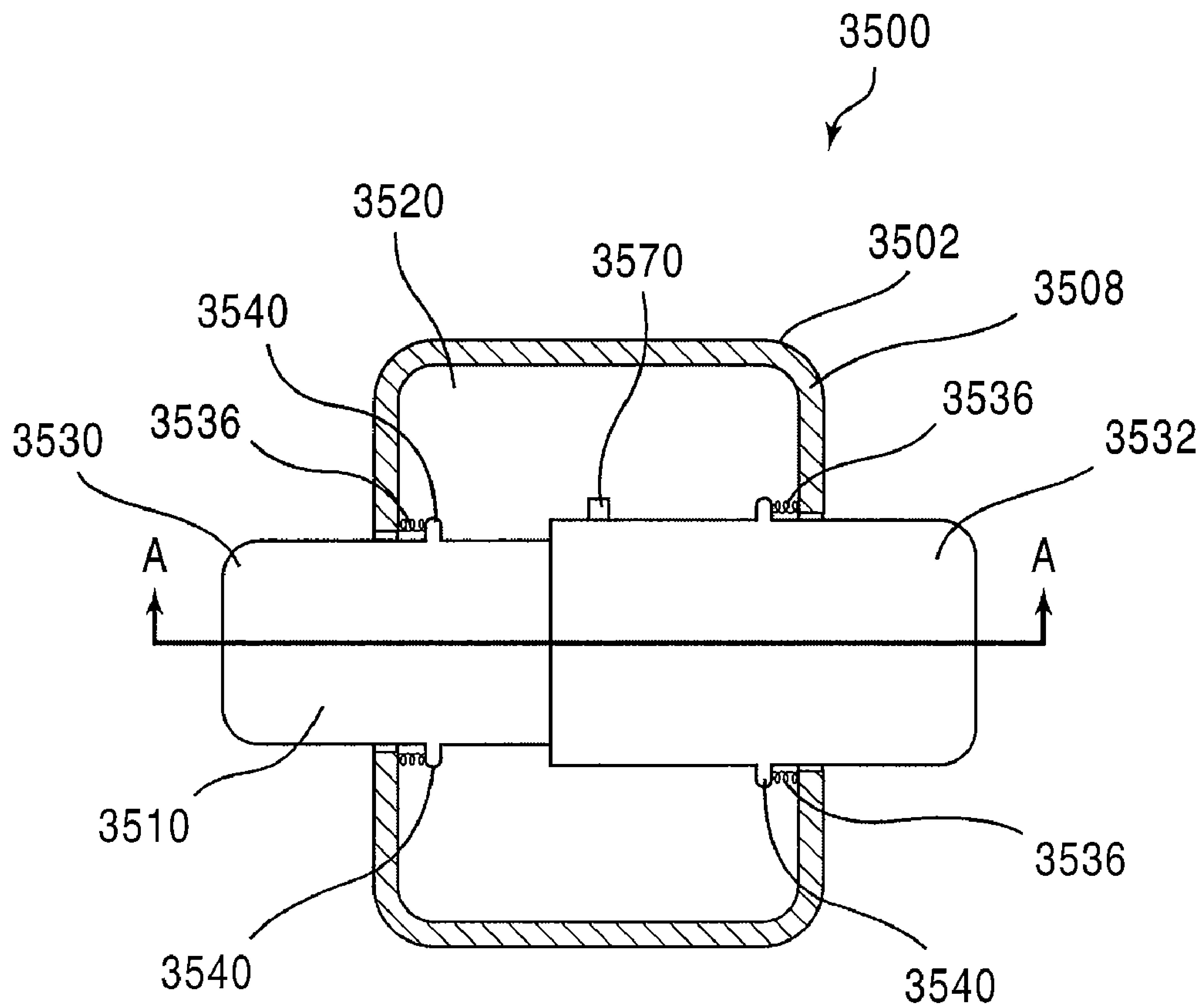

3500
3520
3570
3502
3508
3540
3536
3536
3530
3532
A
A
3510
3536
3540
3540

FIG.77

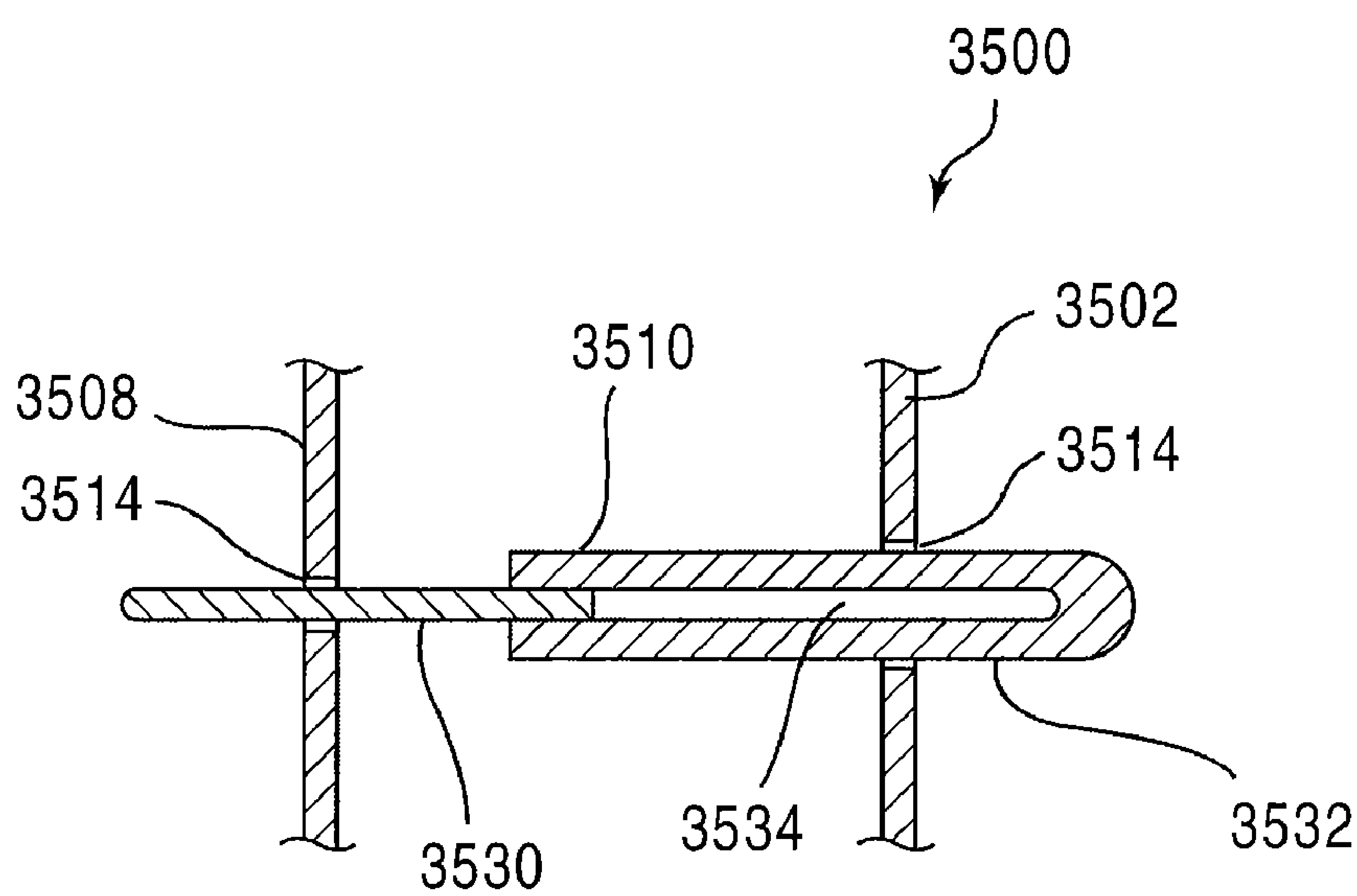

3500
3502
3510
3508
3514
3514
3530
3534
3532

FIG.78

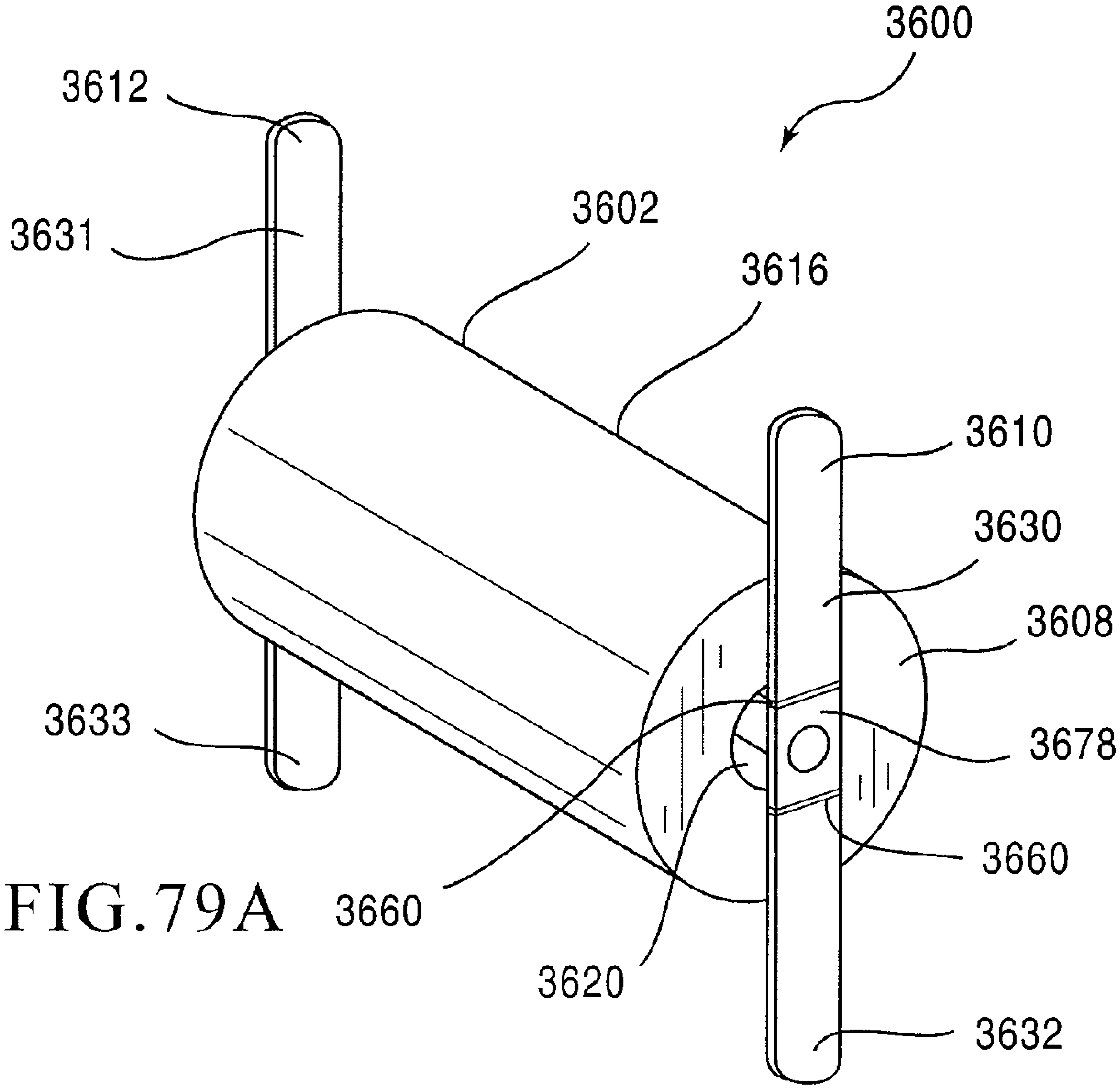


FIG.79A

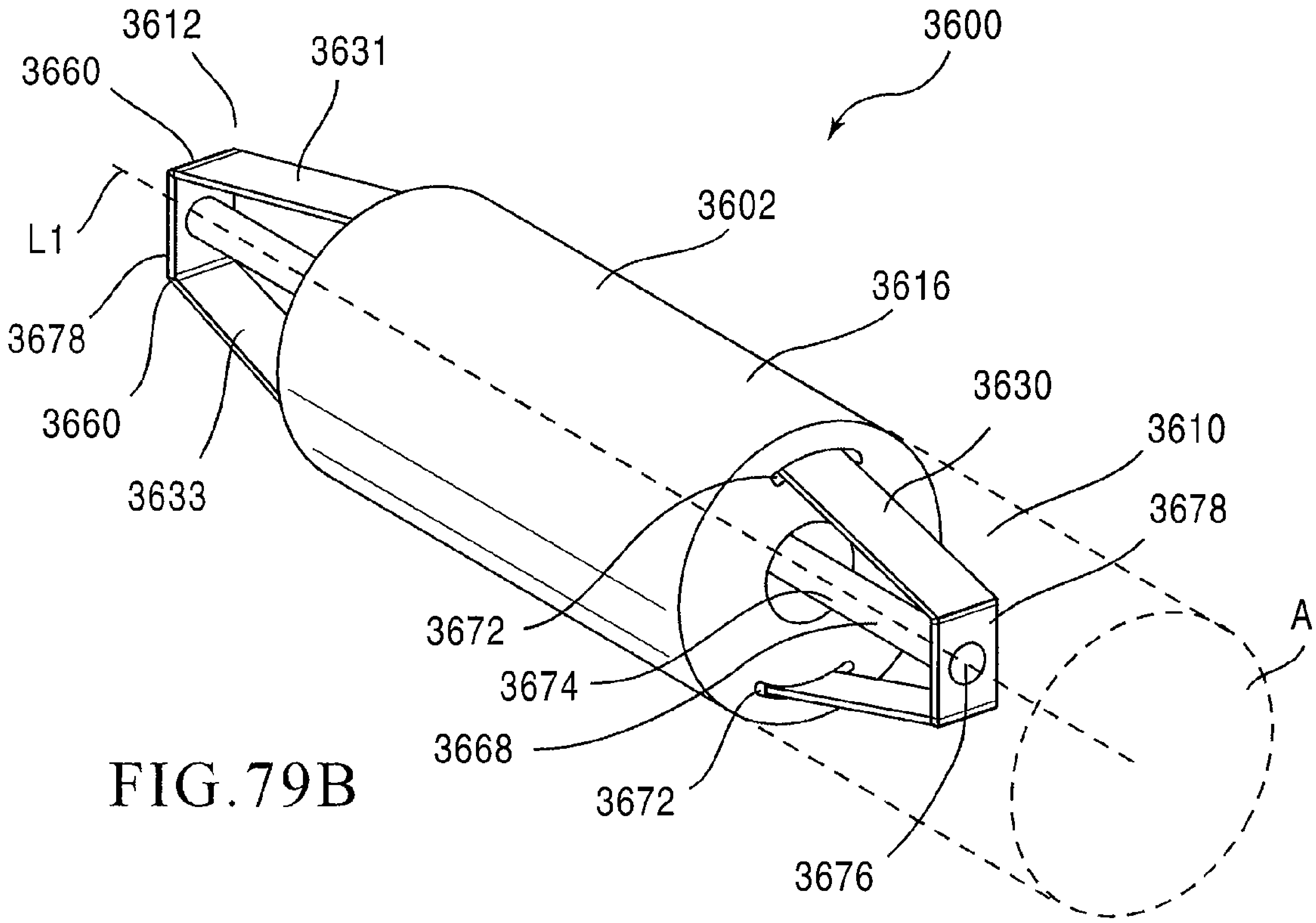


FIG.79B

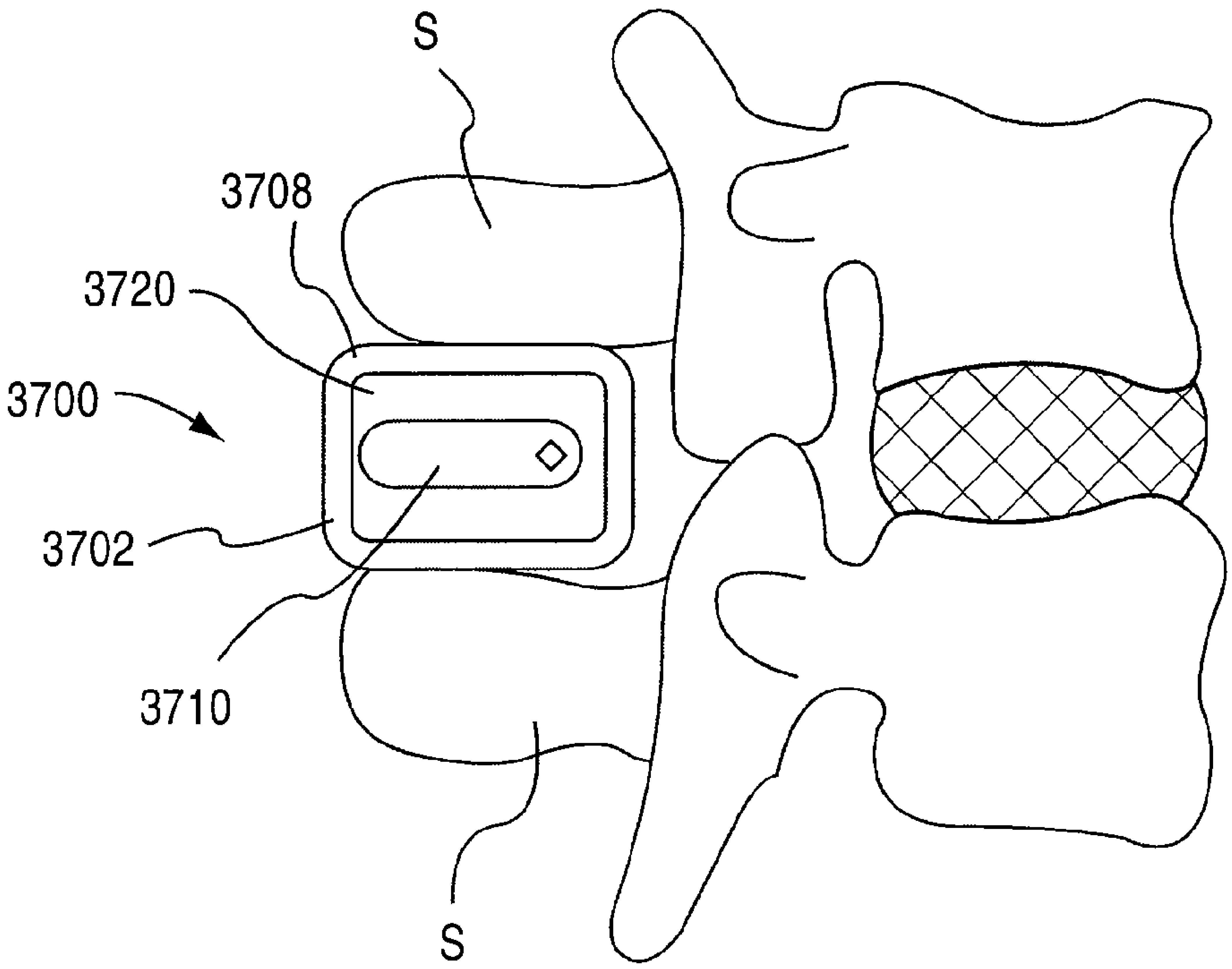


FIG.80A

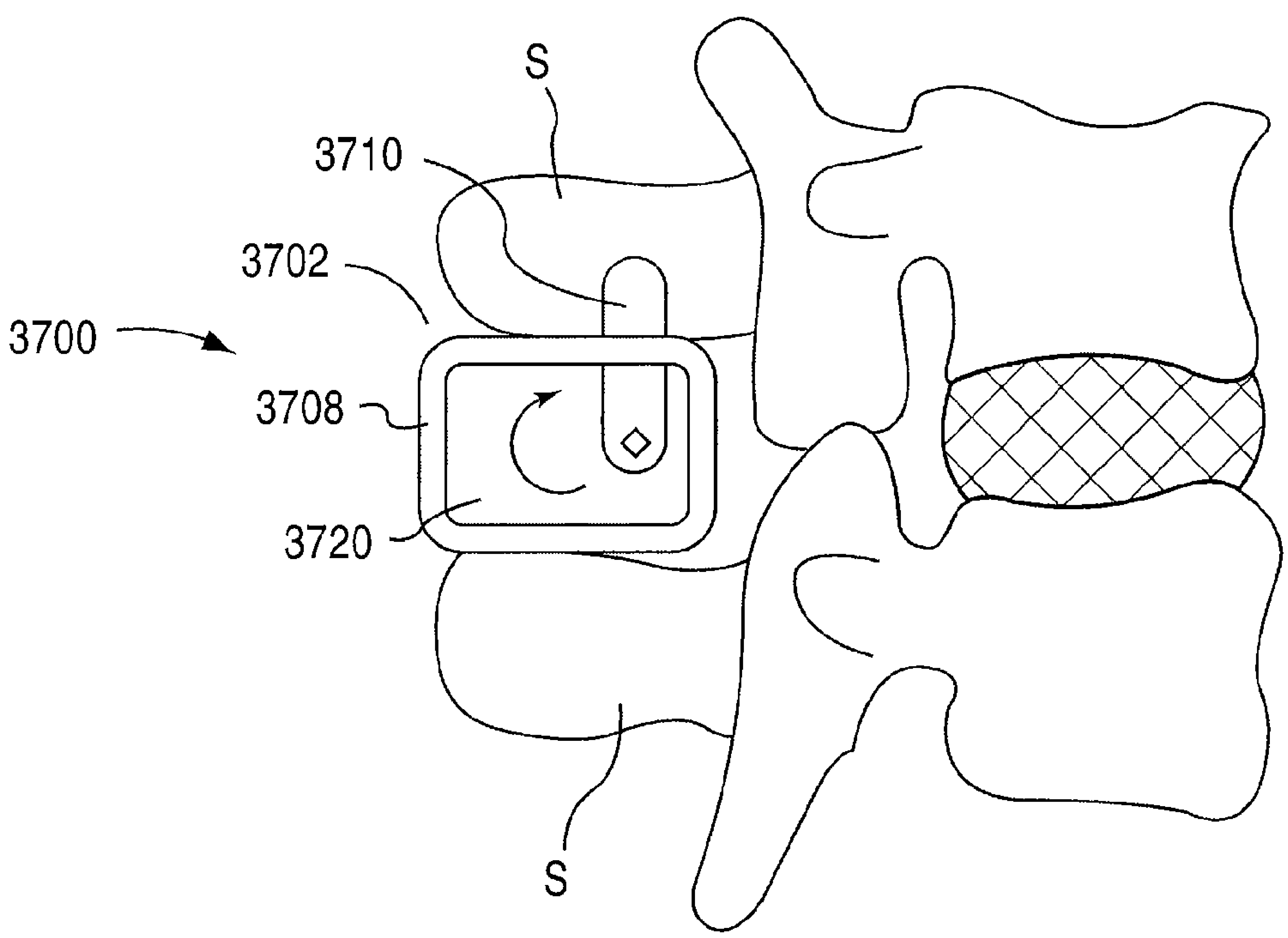


FIG.80B

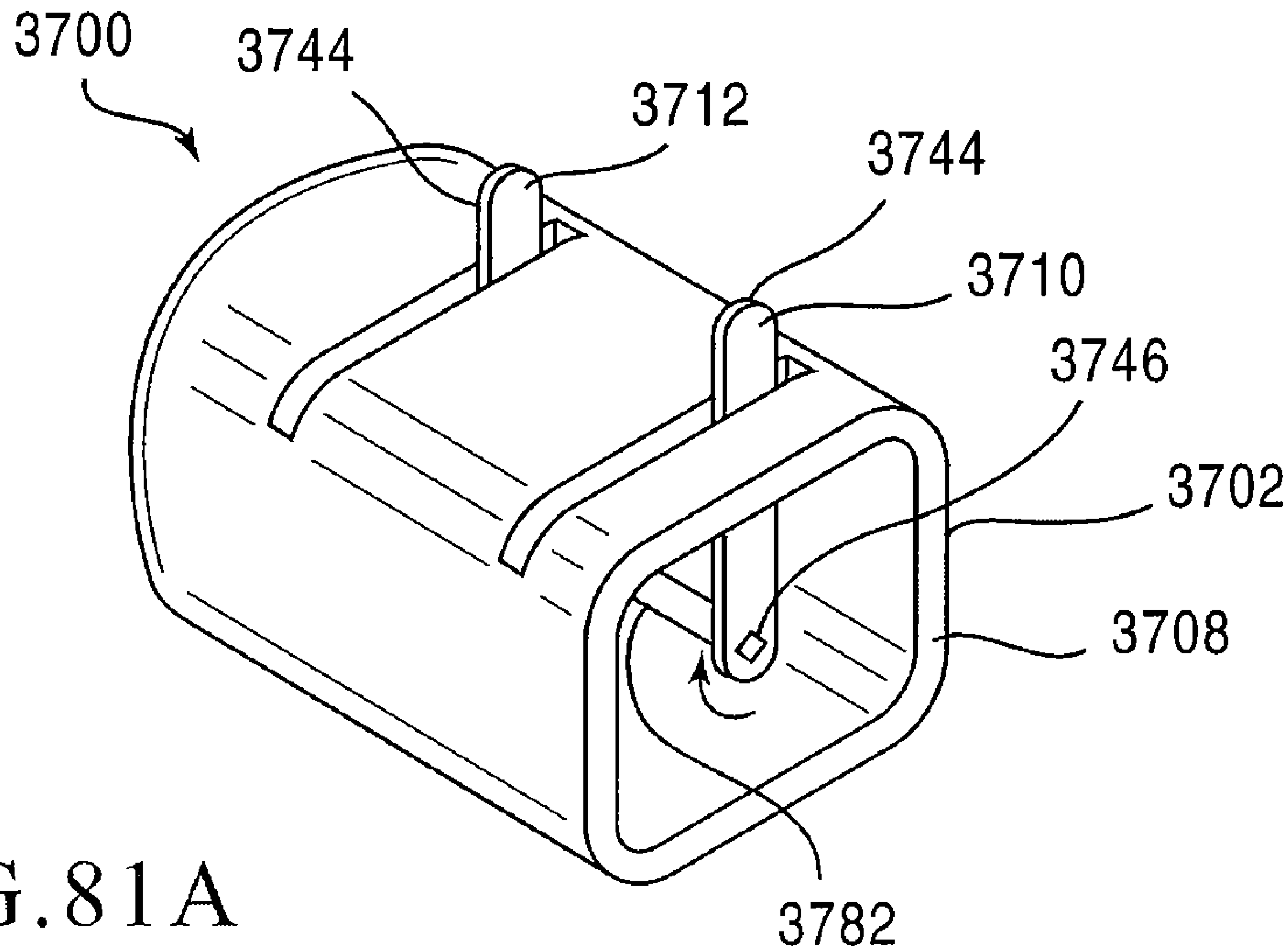


FIG.81A

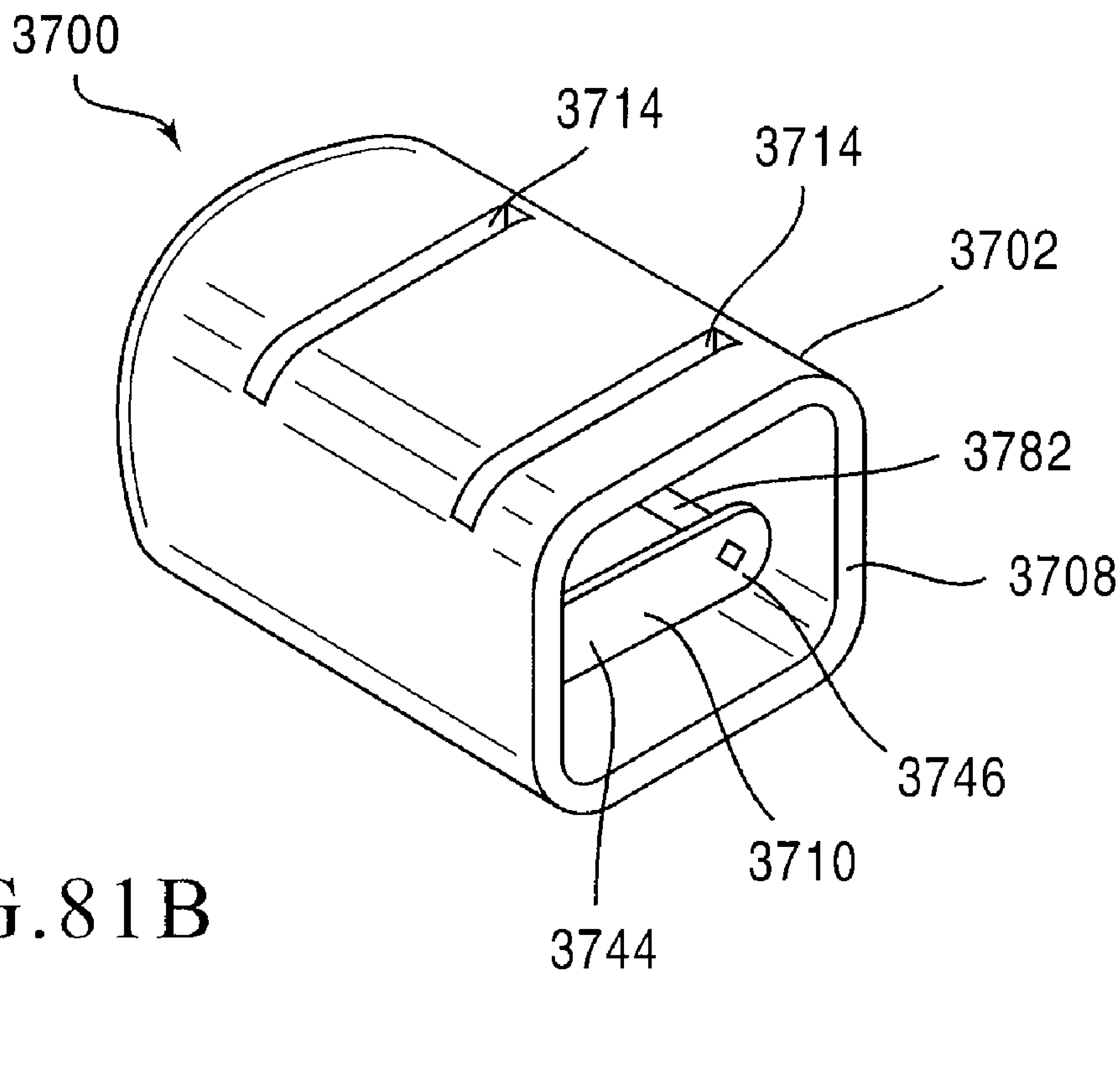


FIG.81B

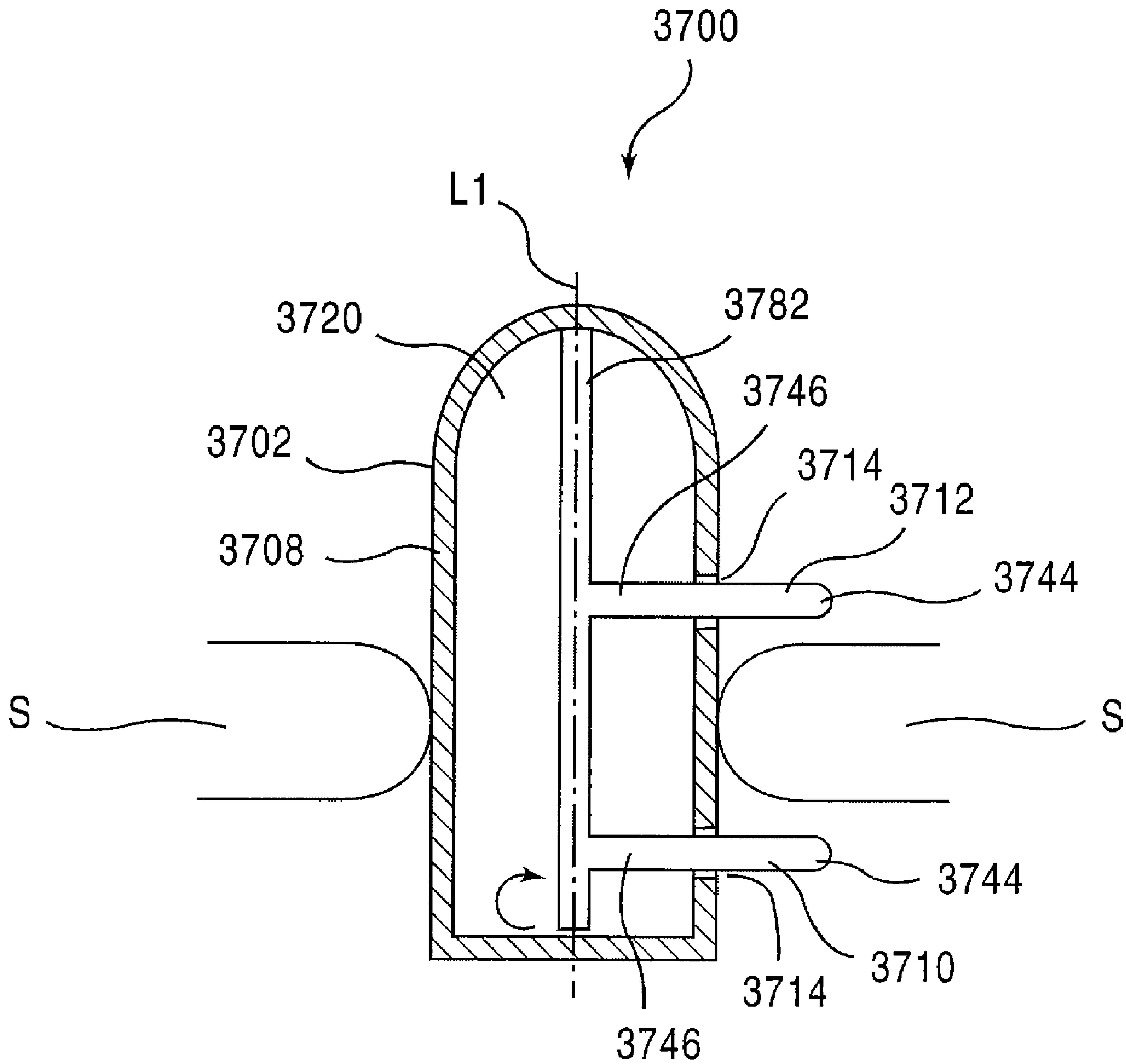

3700
L1
3720
3782
3746
3702
3714
3712
3708
3744
S
S
3744
3710
3714
3746

FIG.82

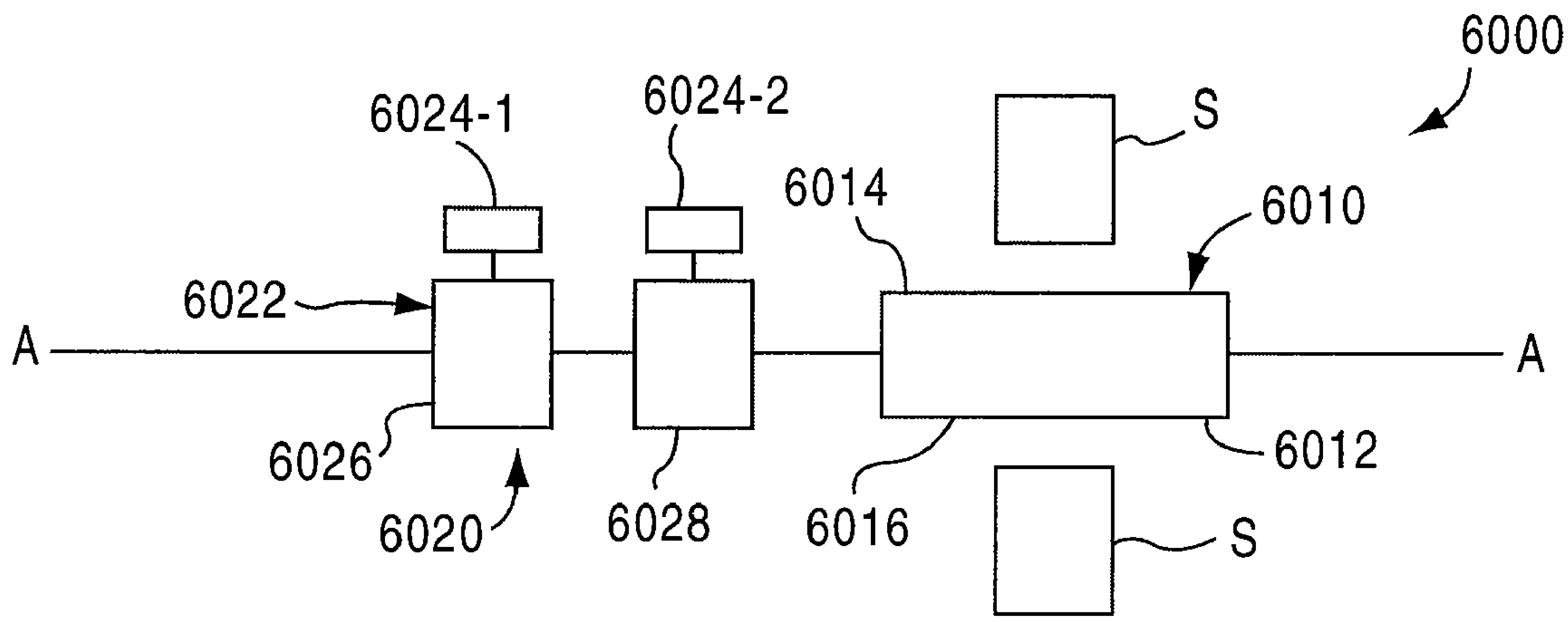

6000
6024-1
6024-2
S
6014
6010
6022
A
A
6026
6012
6020
6028
6016
S

FIG.83

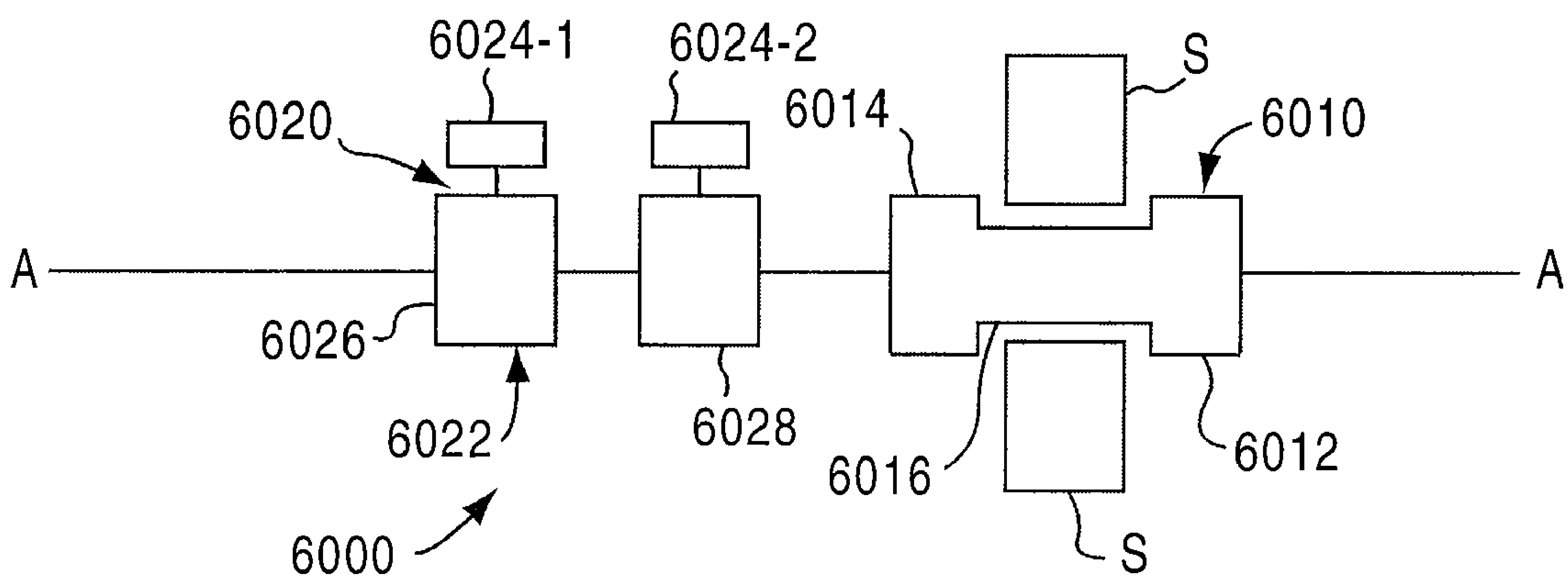

6024-1
6024-2
S
6020
6014
6010
A
A
6026
6022
6028
6016
6012
6000
S

FIG.84

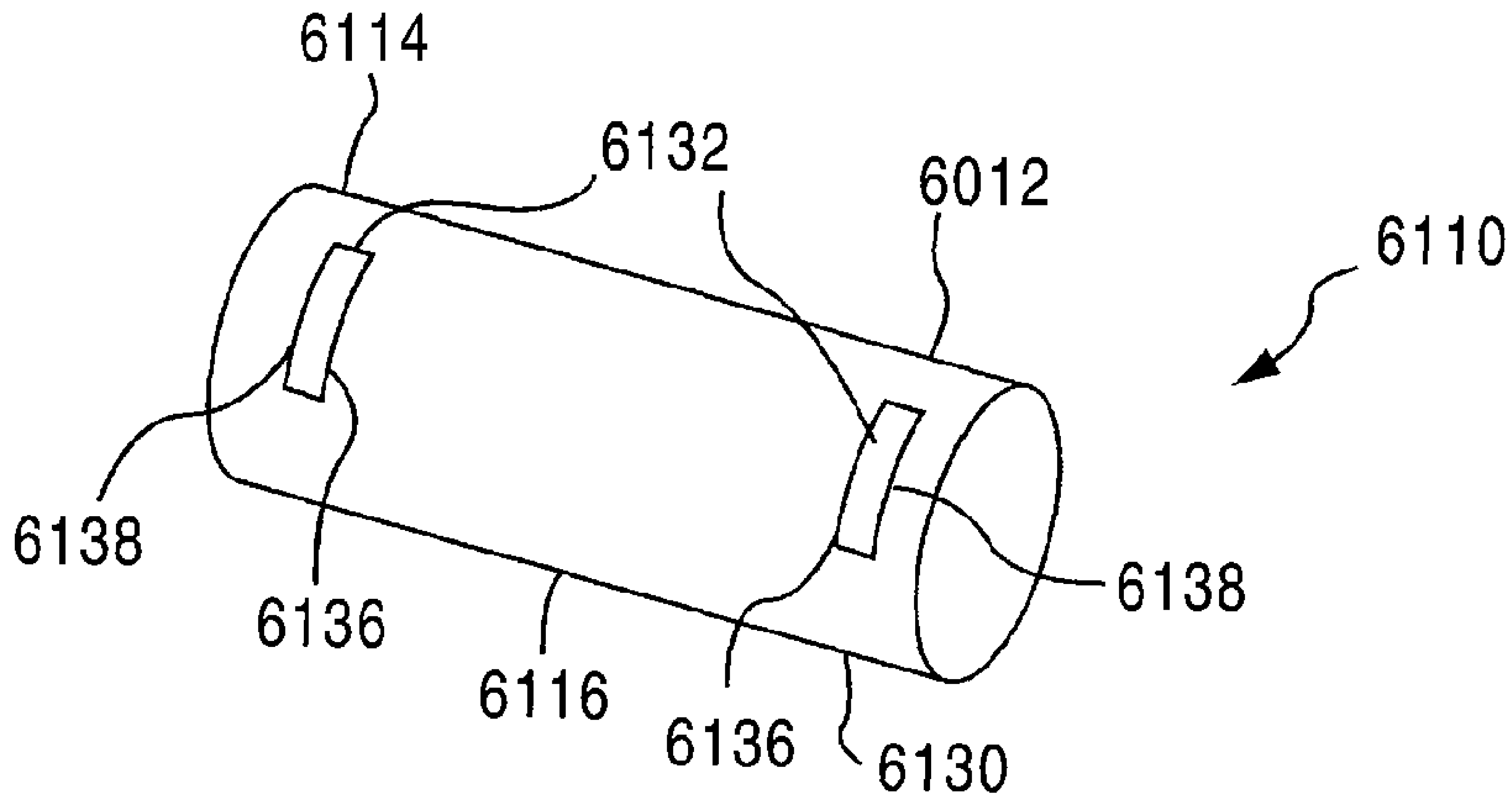


FIG.85

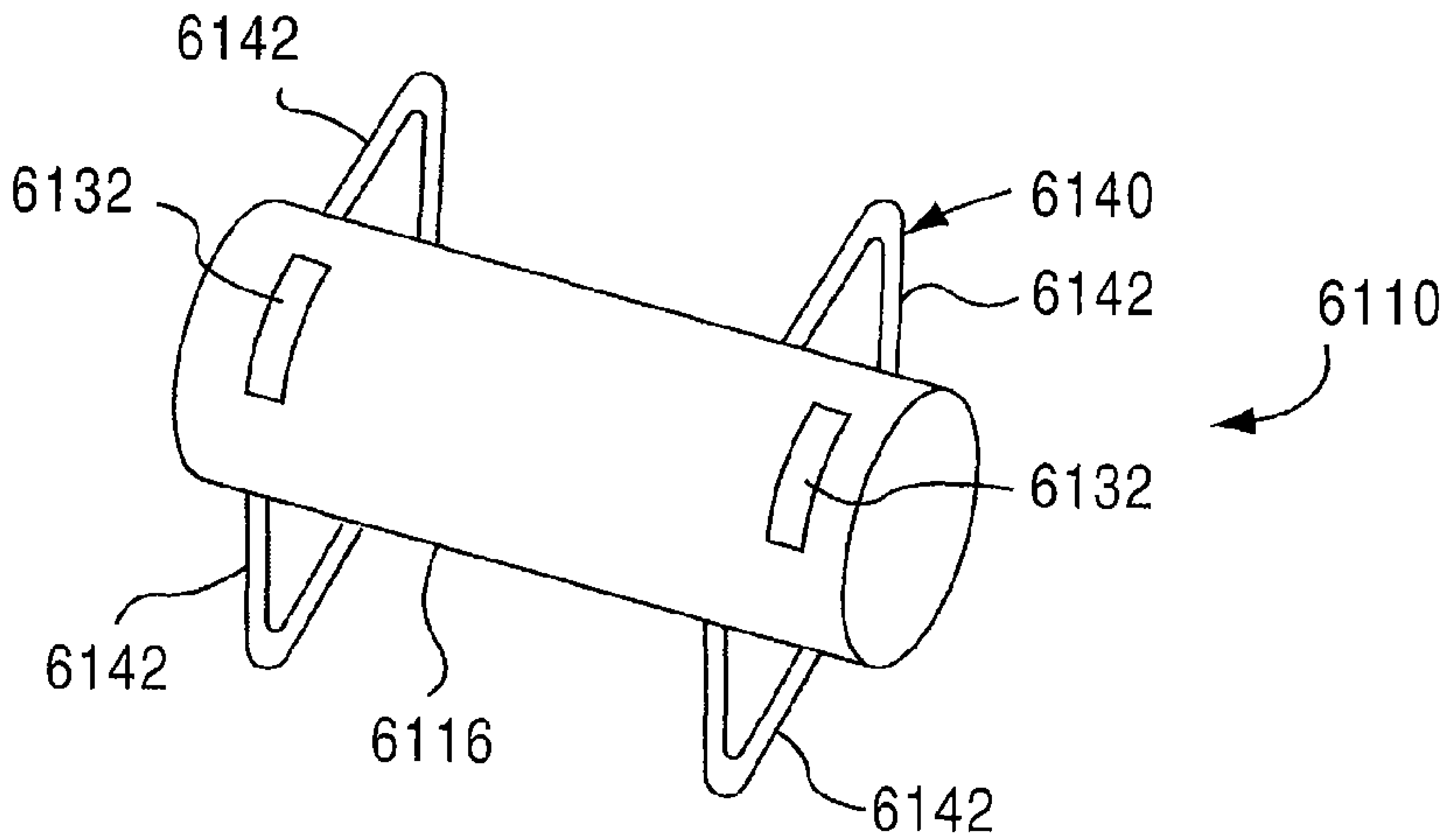


FIG.86

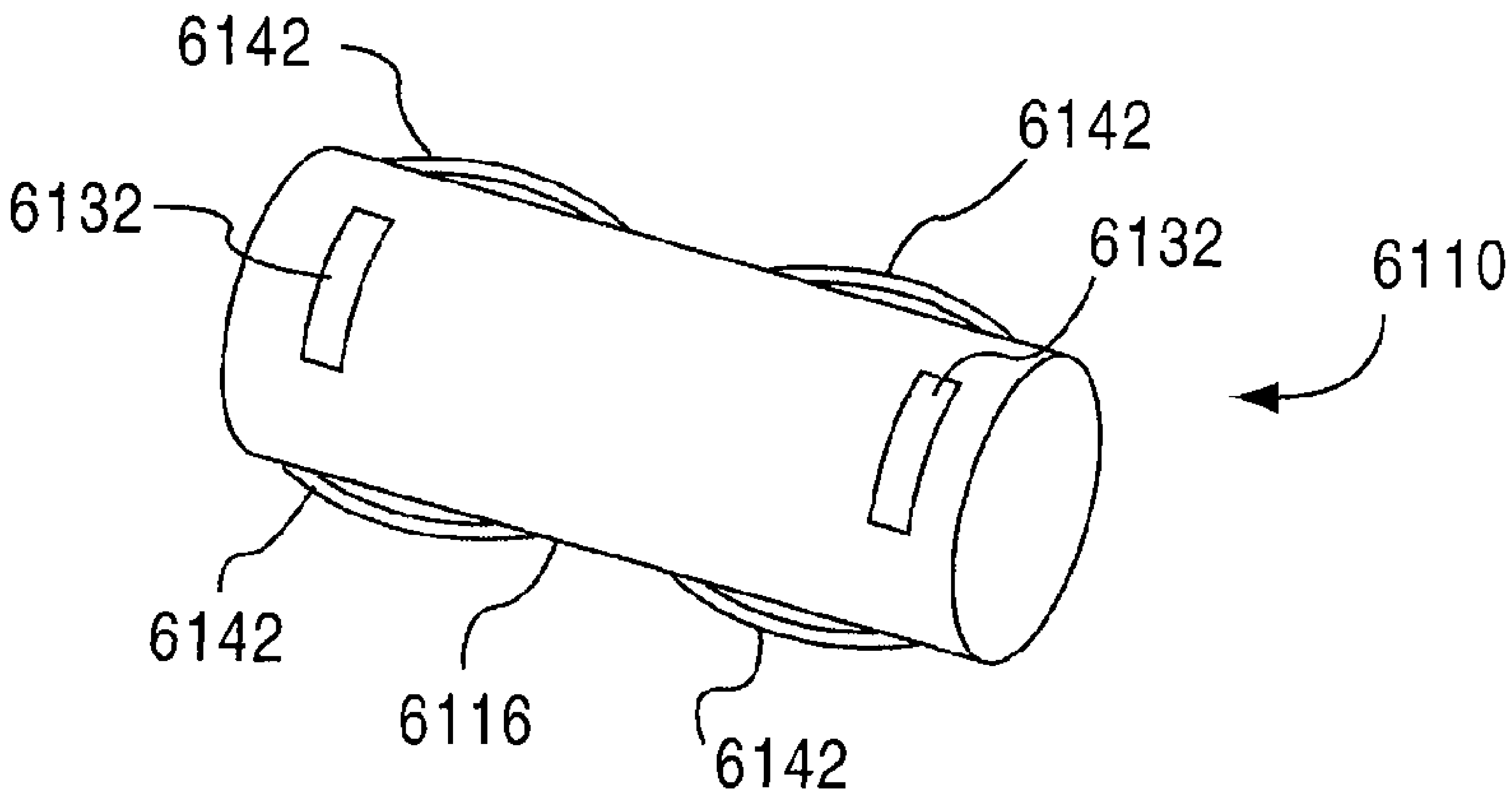


FIG.87

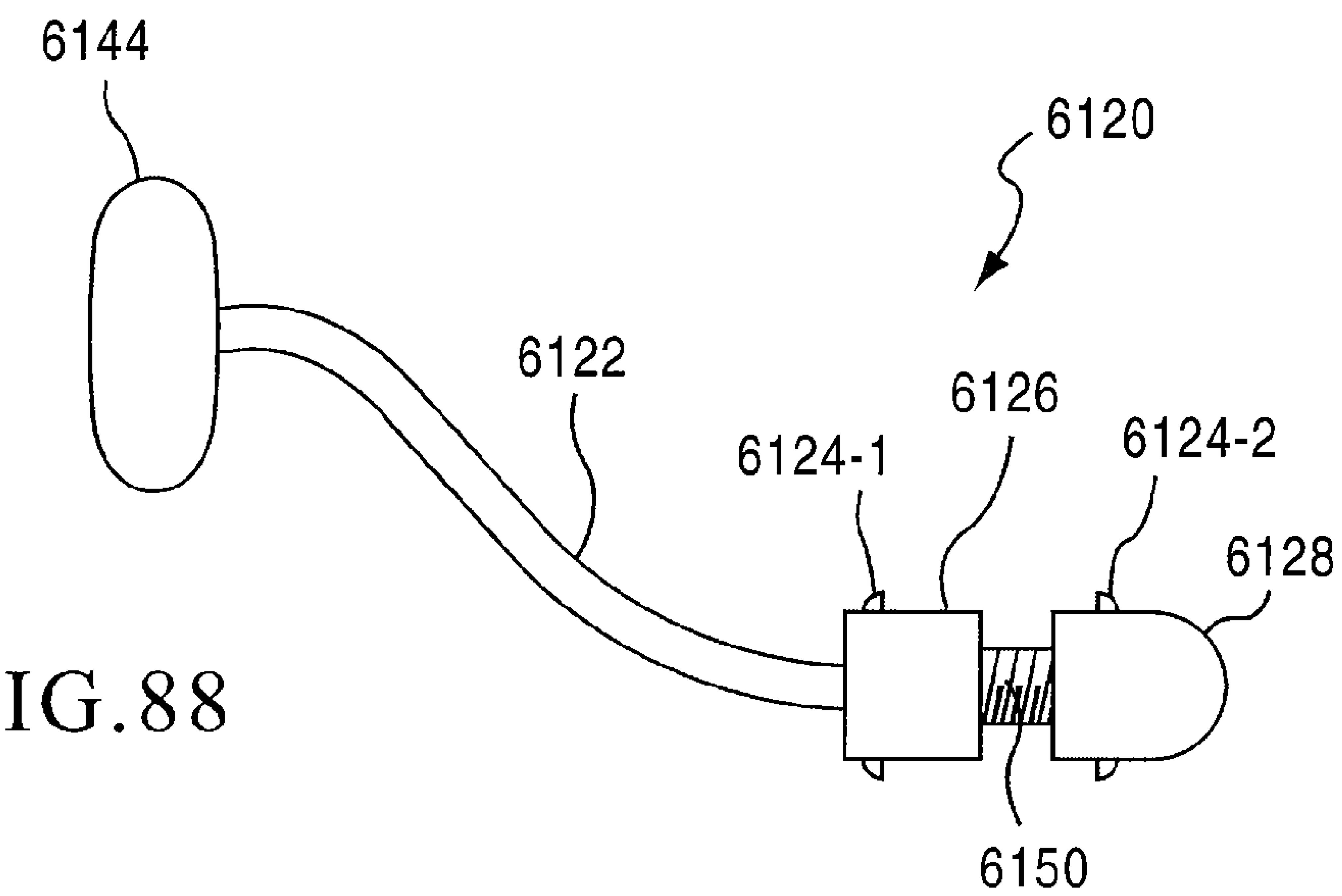


FIG.88

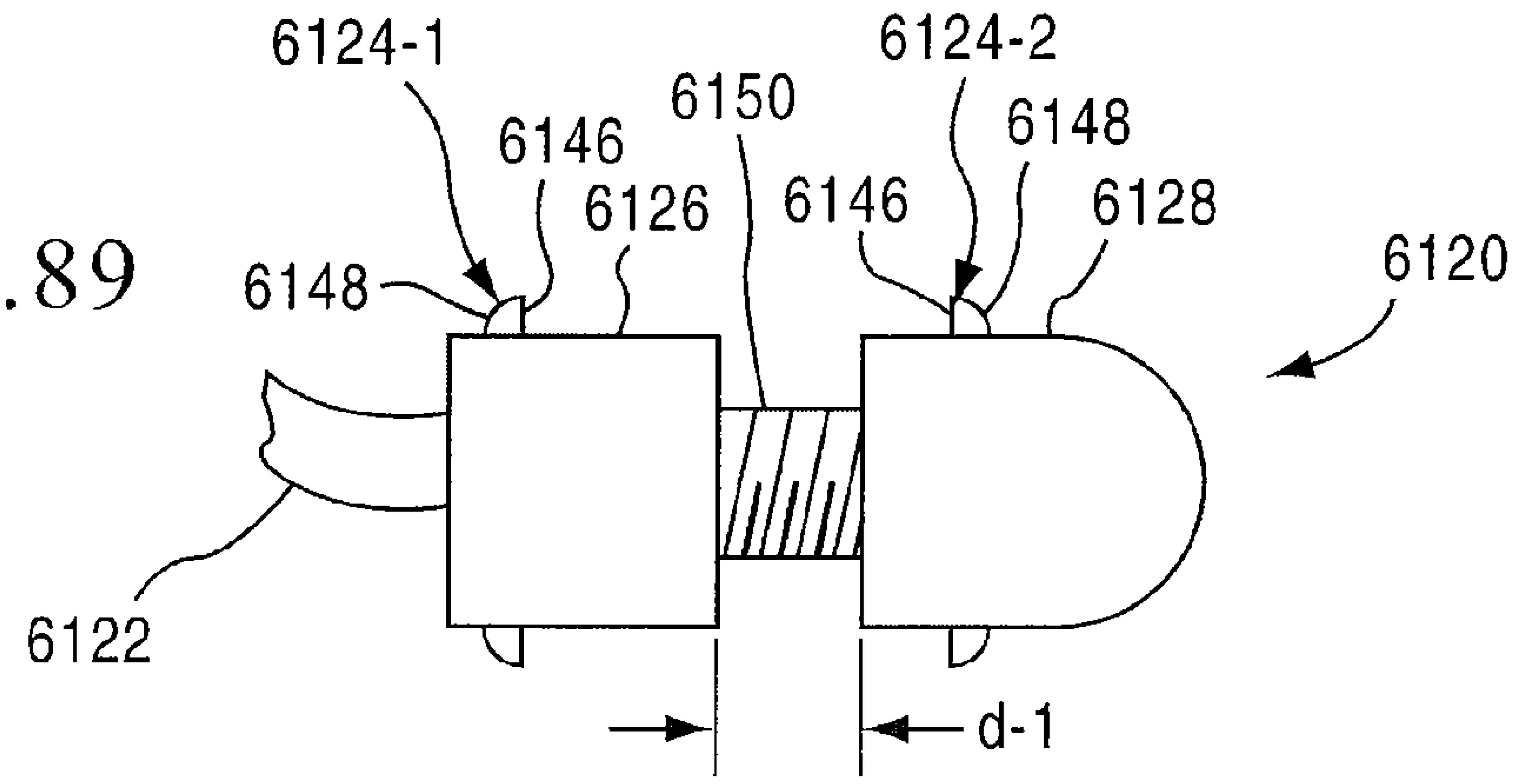


FIG.89

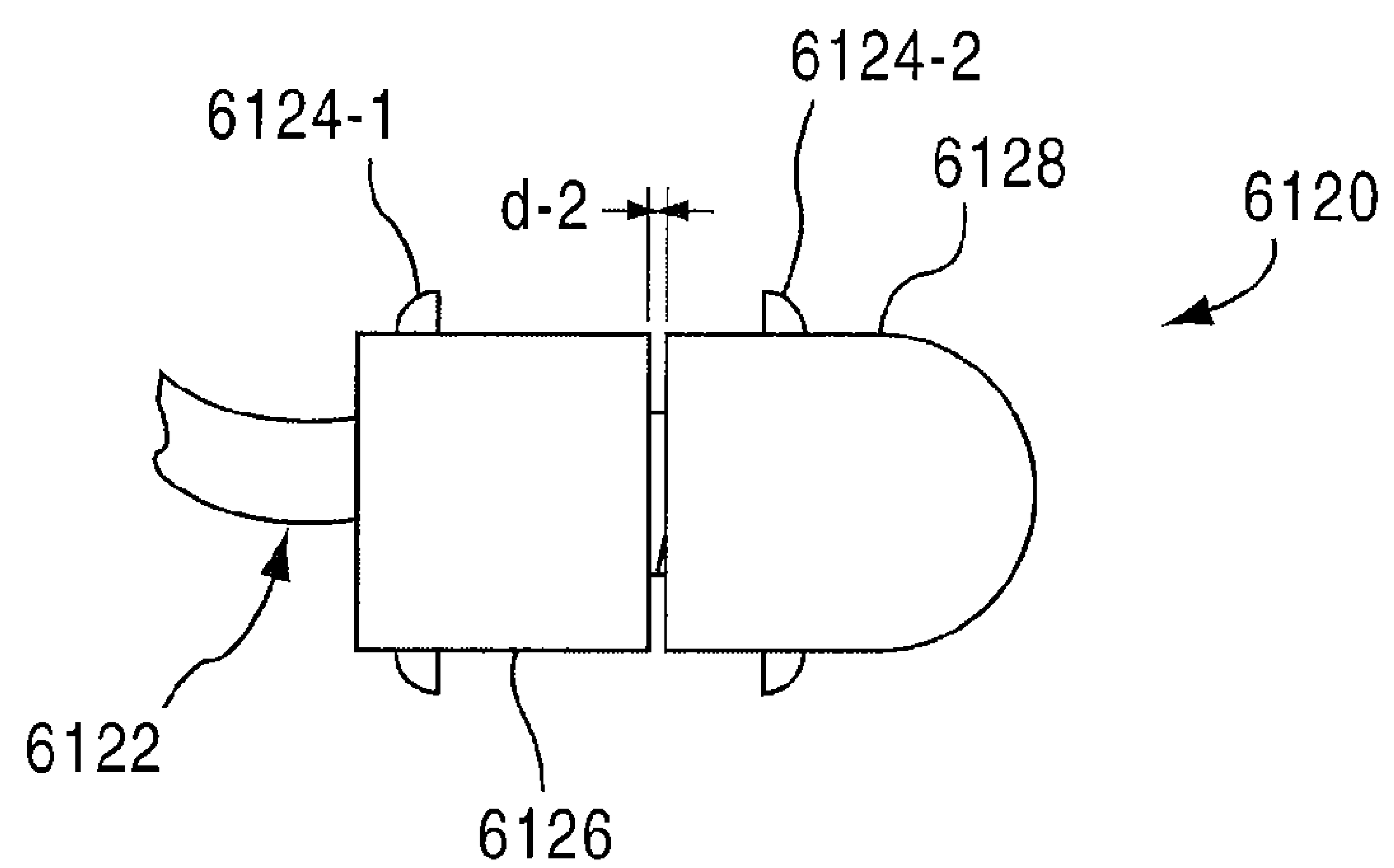


FIG.90

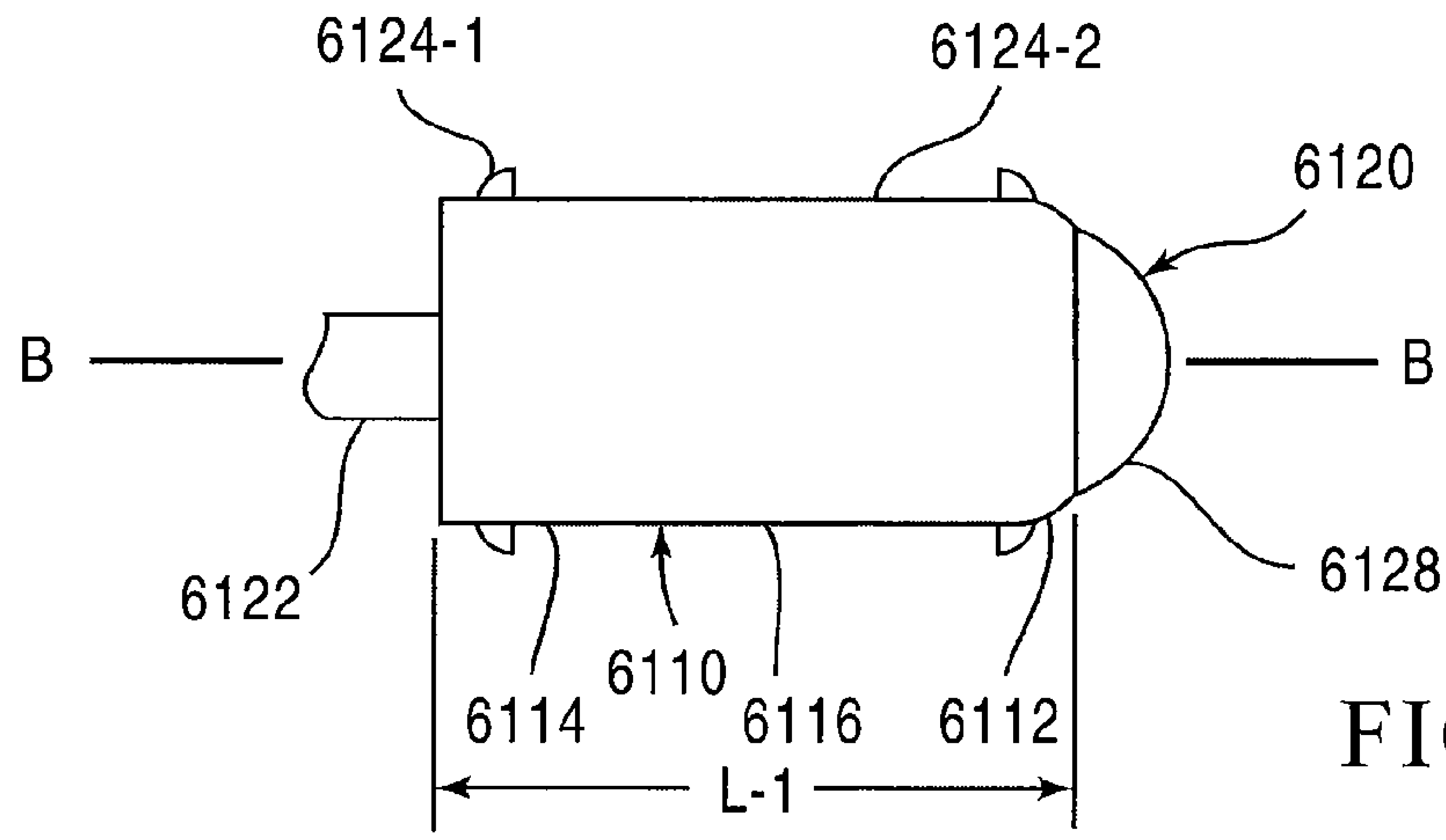


FIG.91

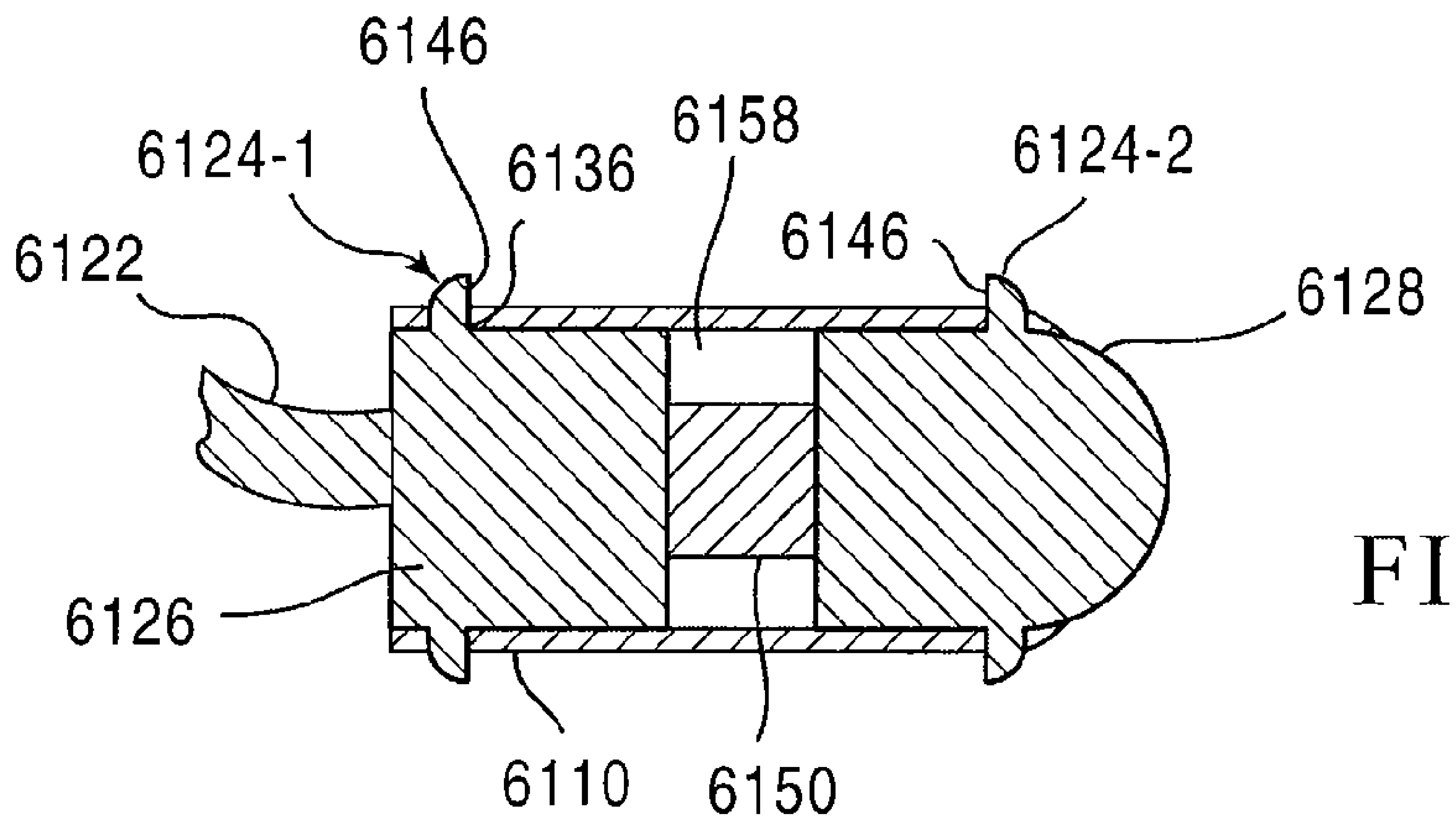


FIG.92

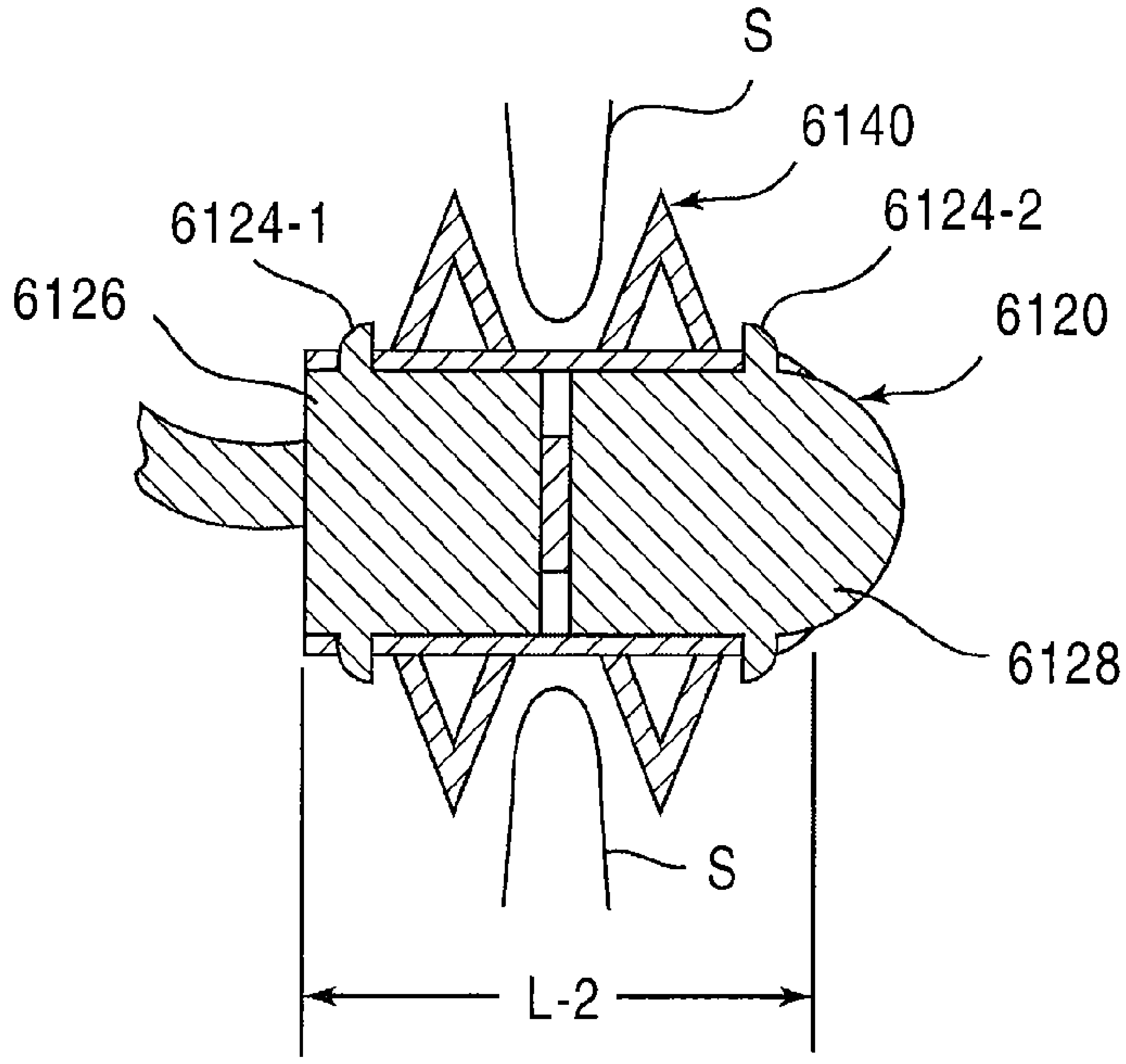


FIG.93

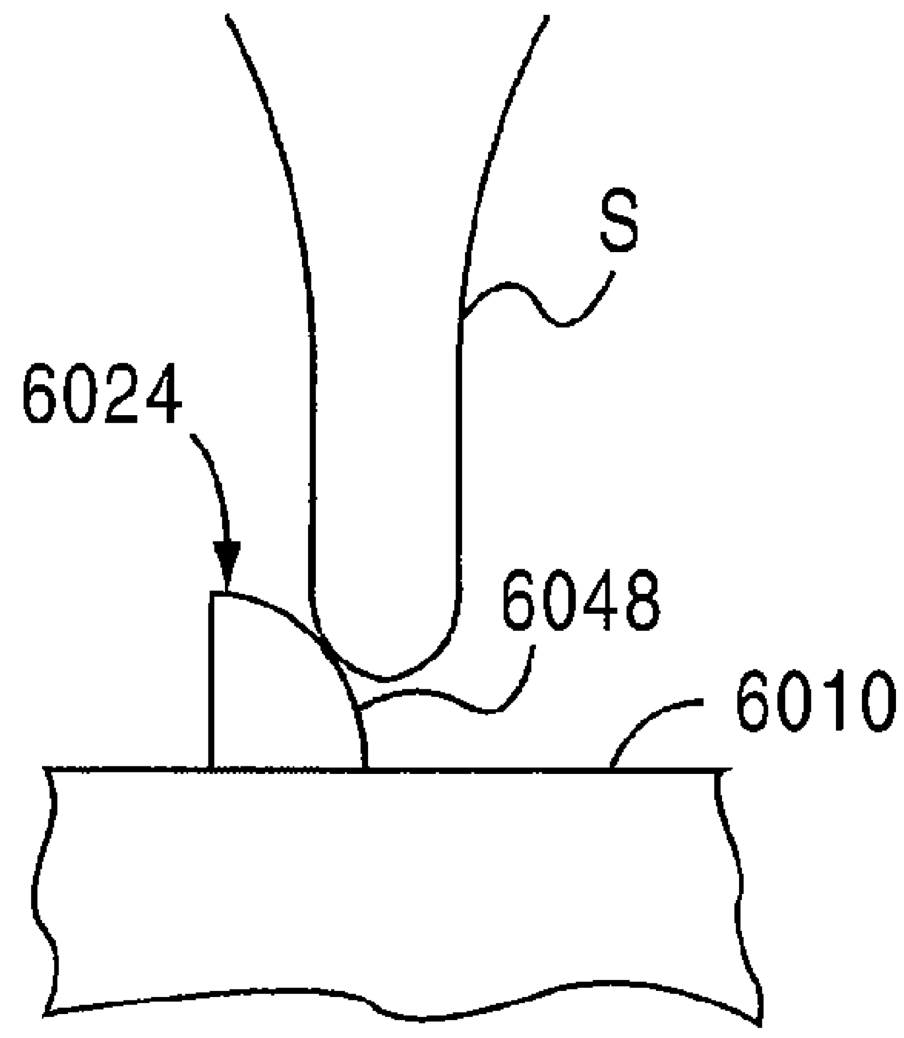


FIG.94

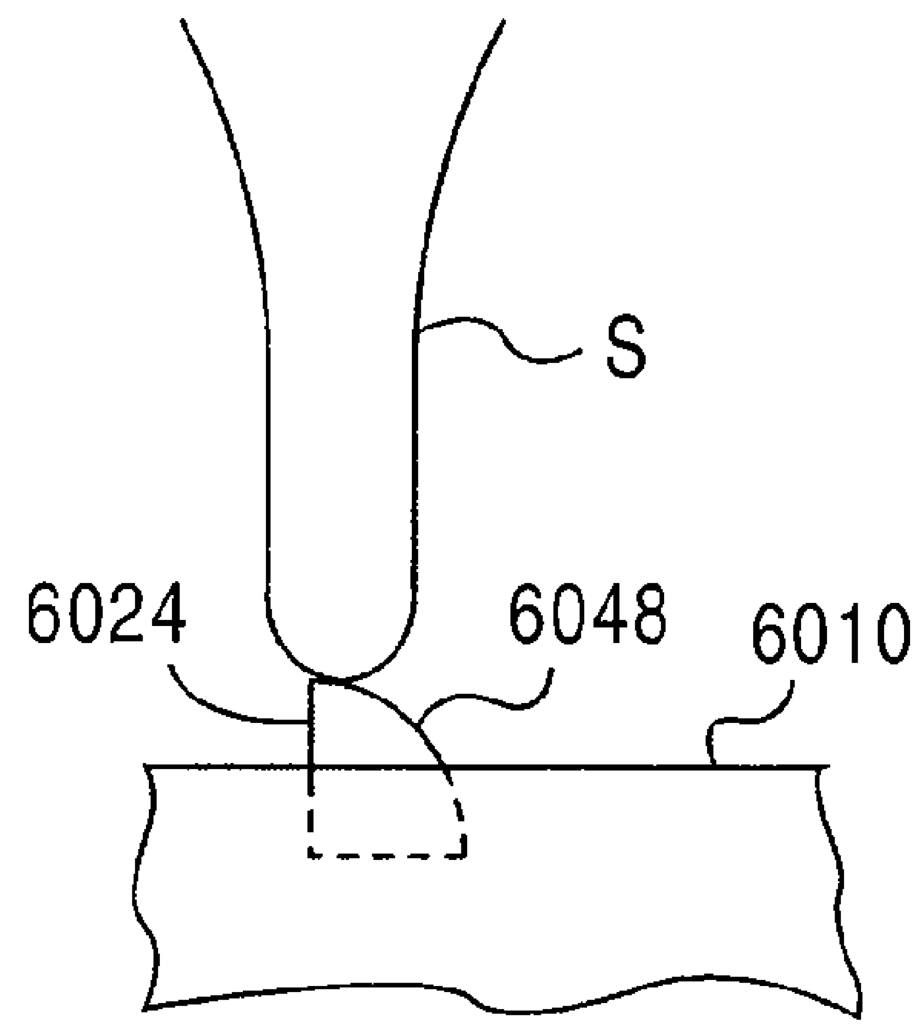


FIG.95

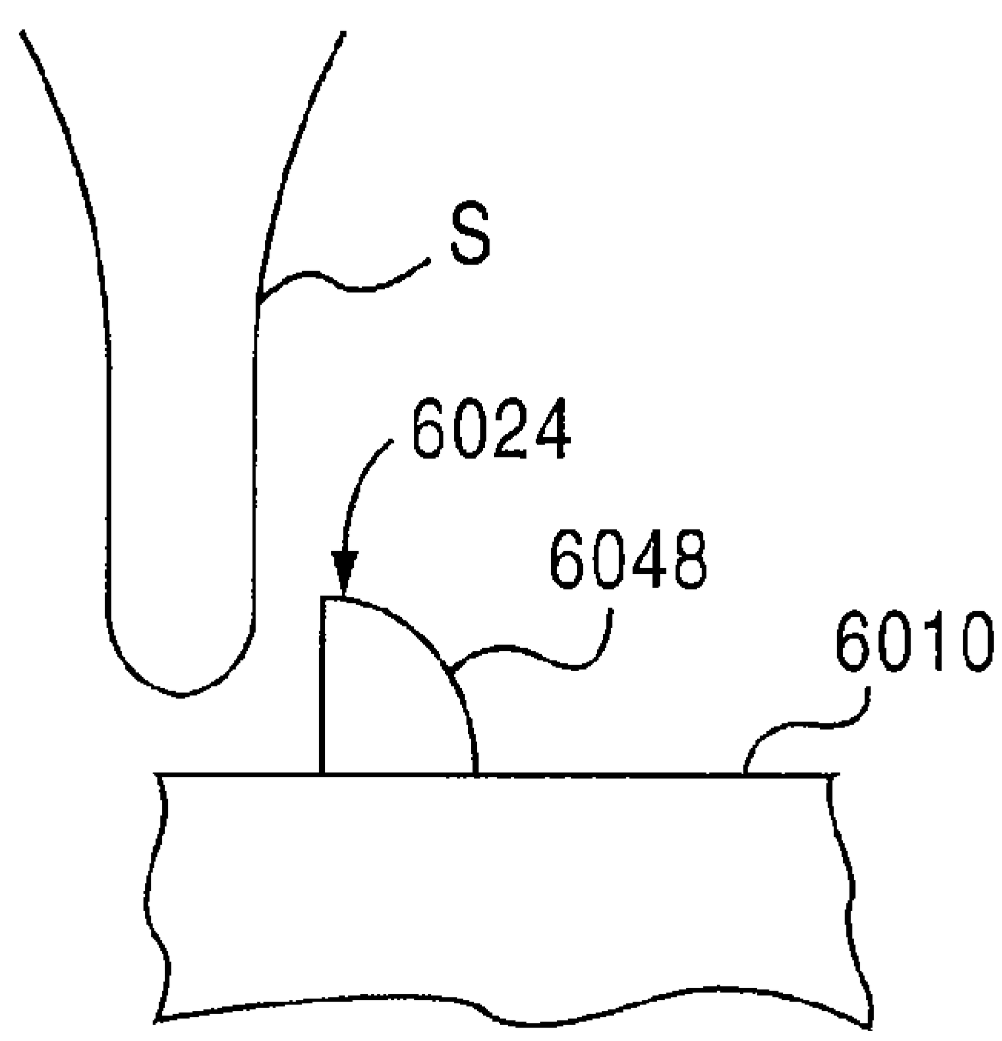


FIG.96

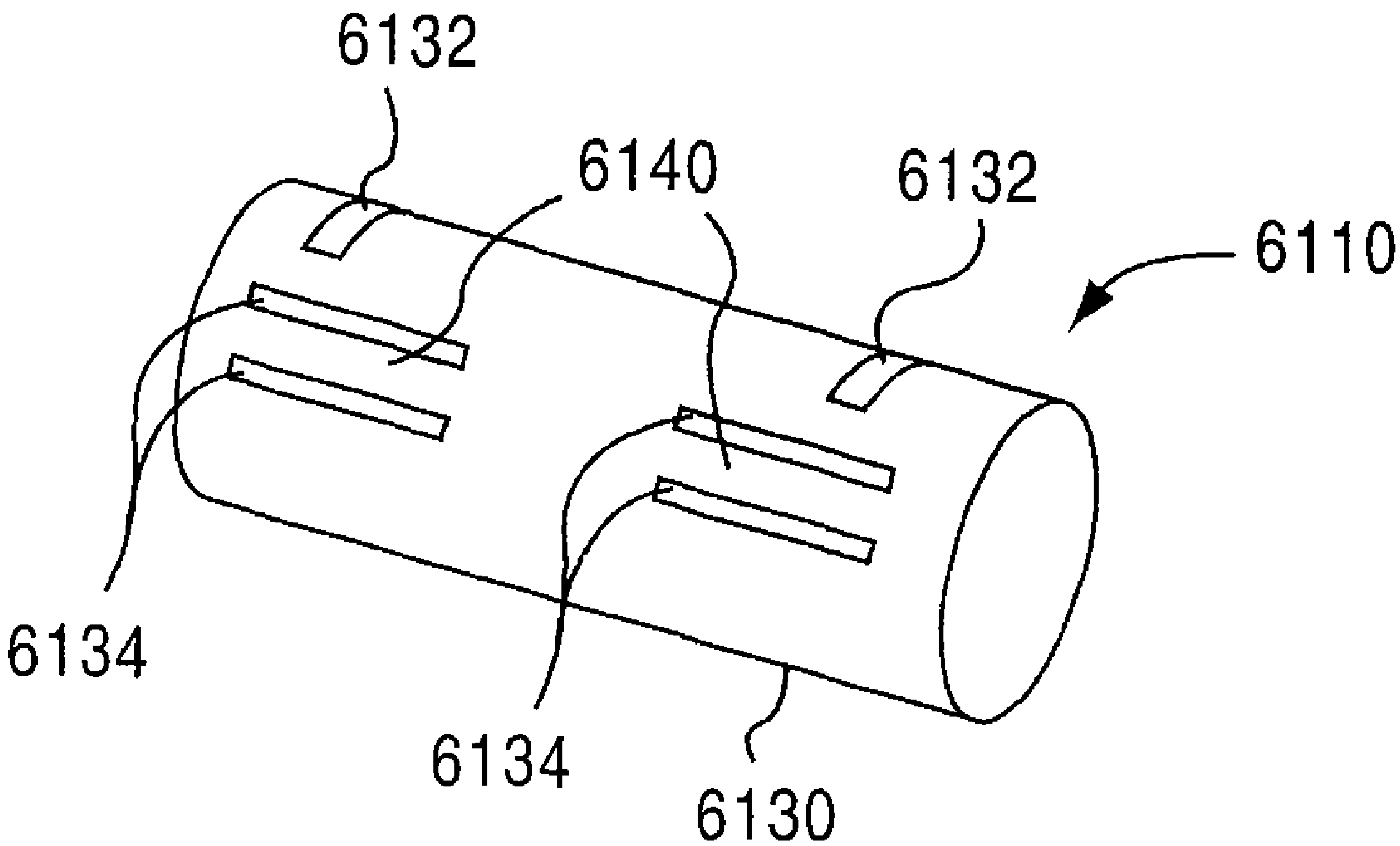


FIG.97

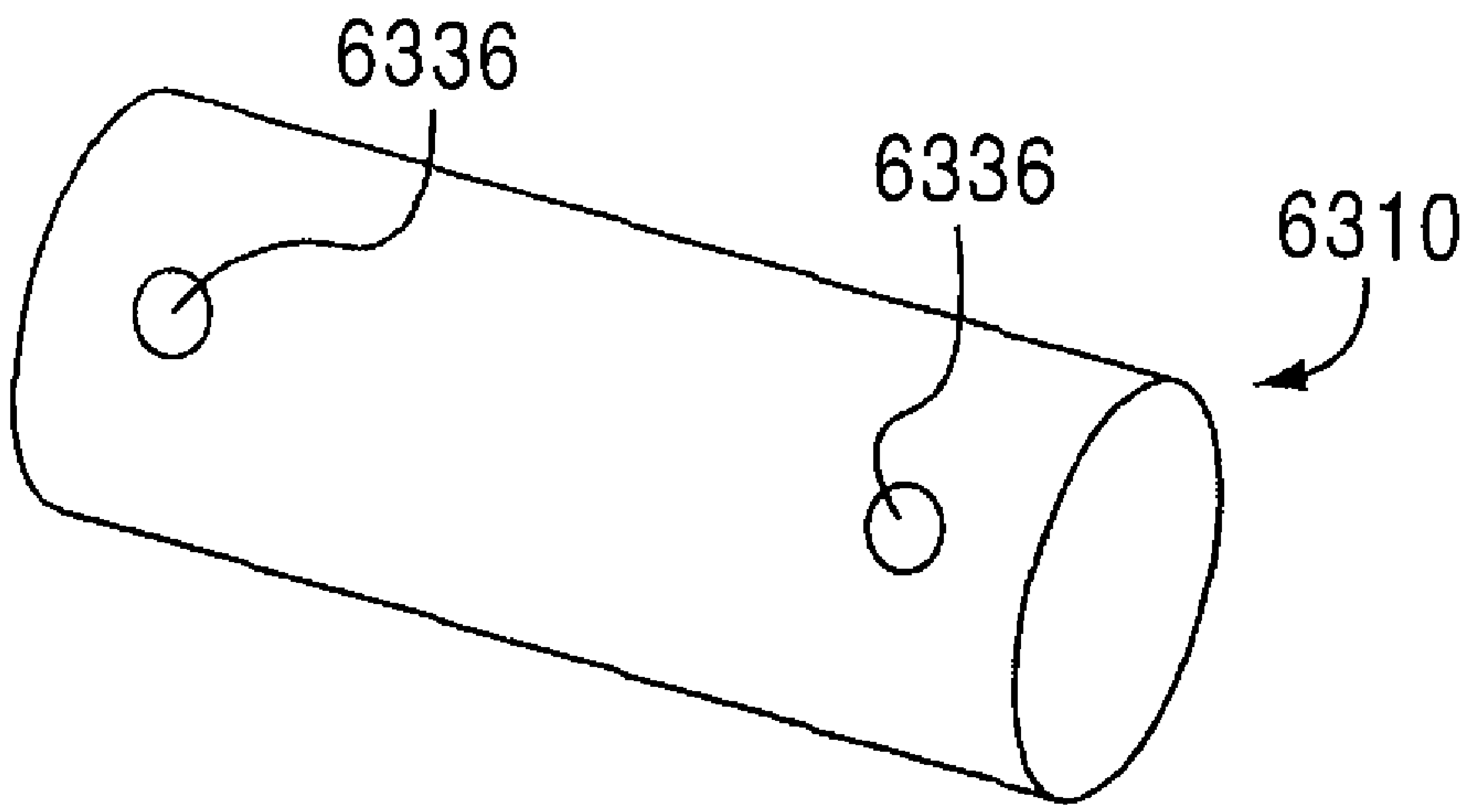


FIG.98

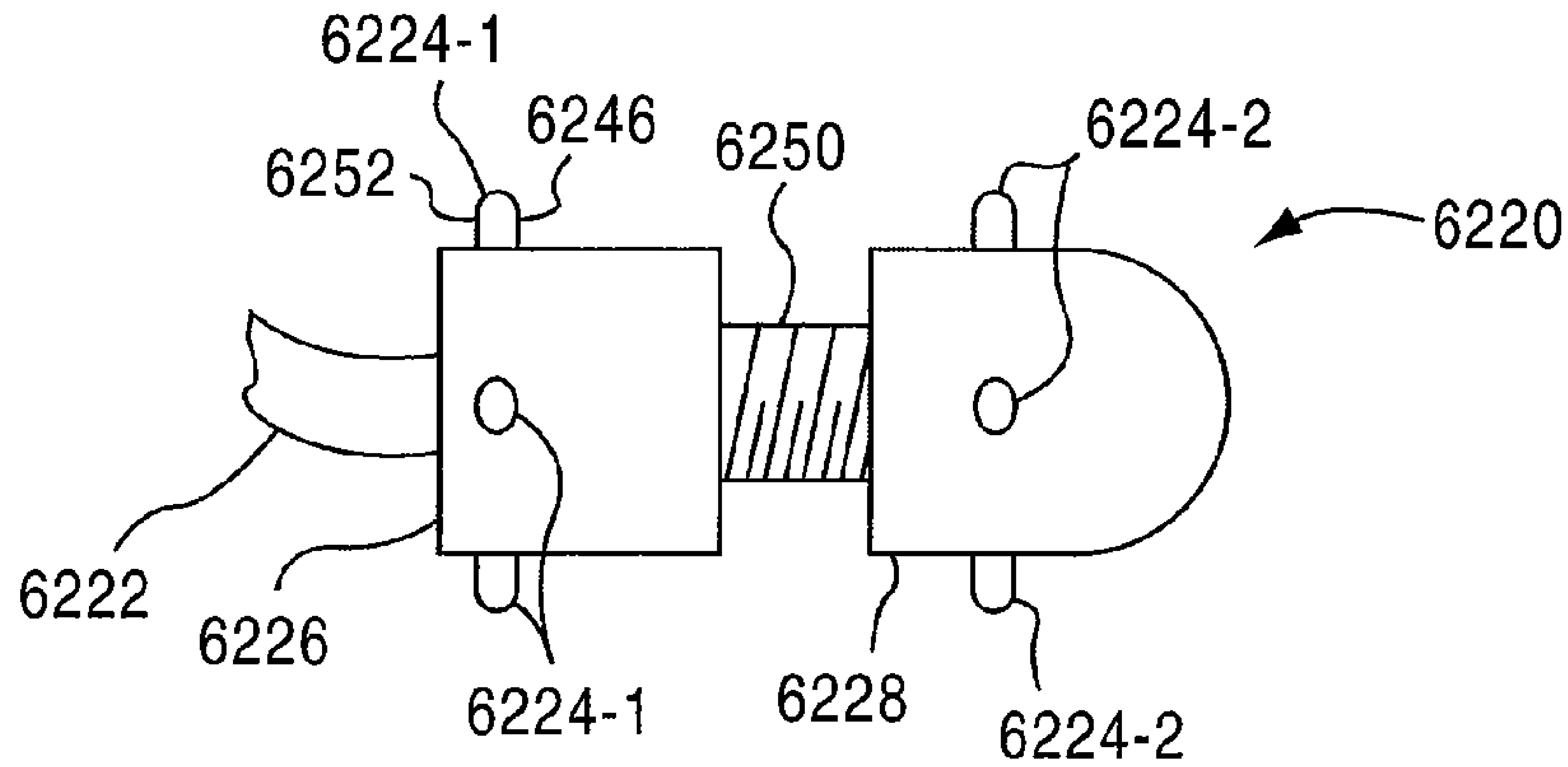


FIG.99

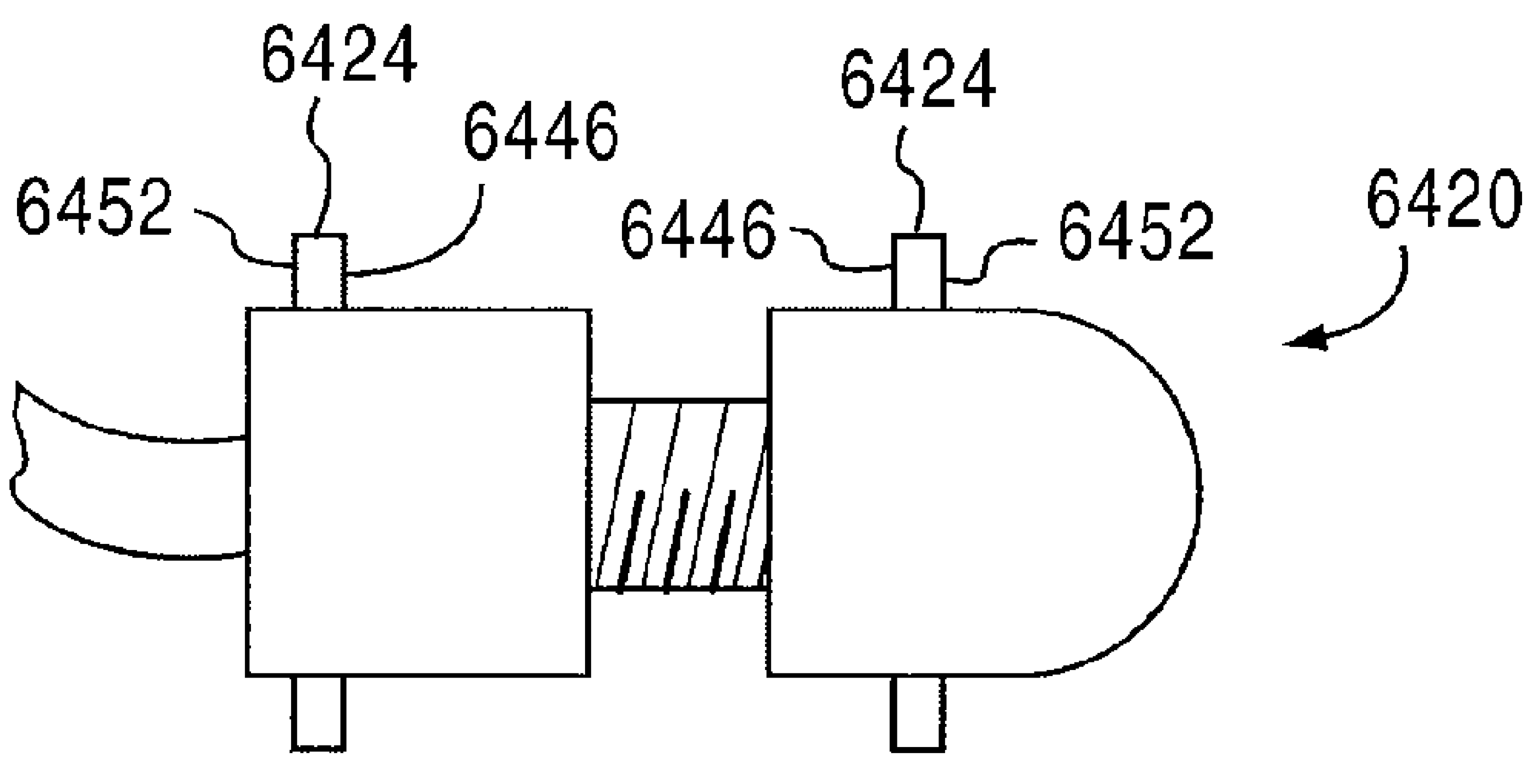


FIG.100

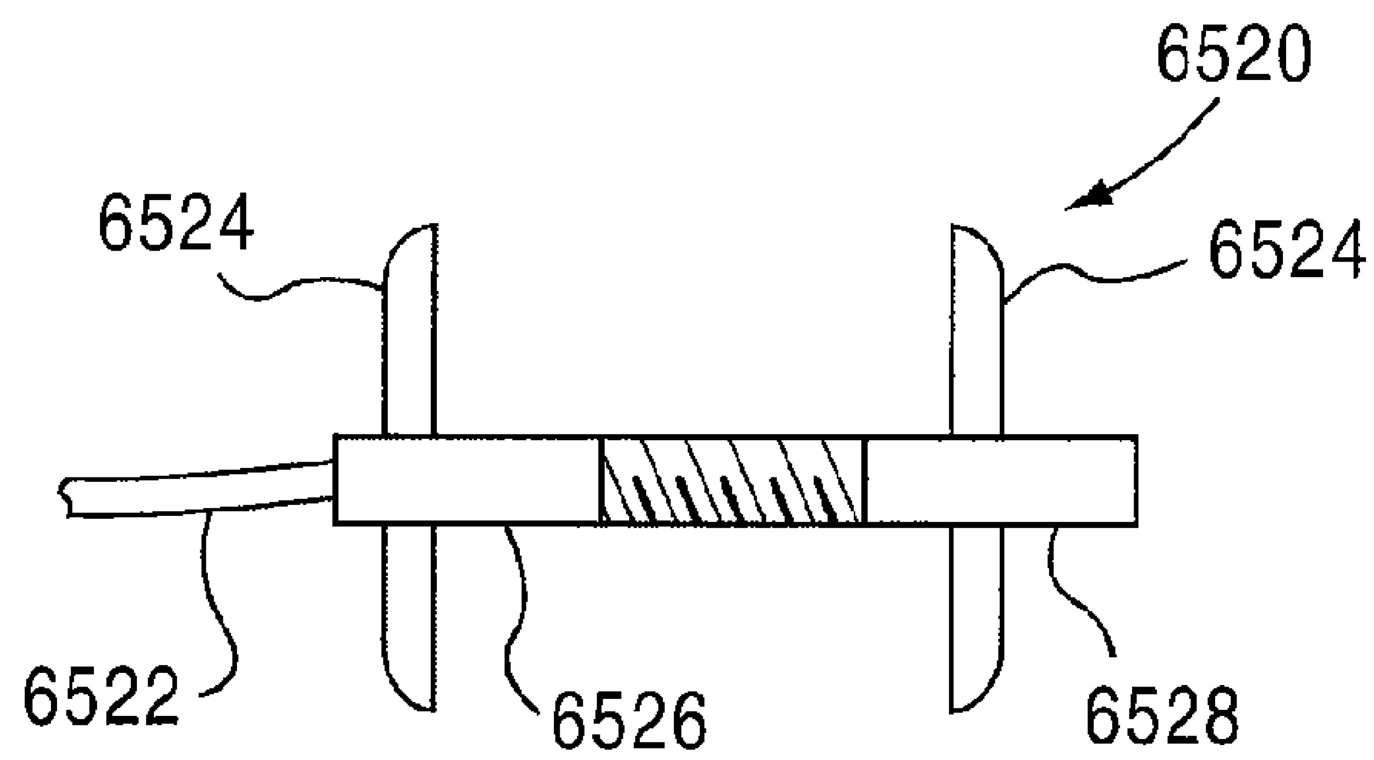


FIG.101

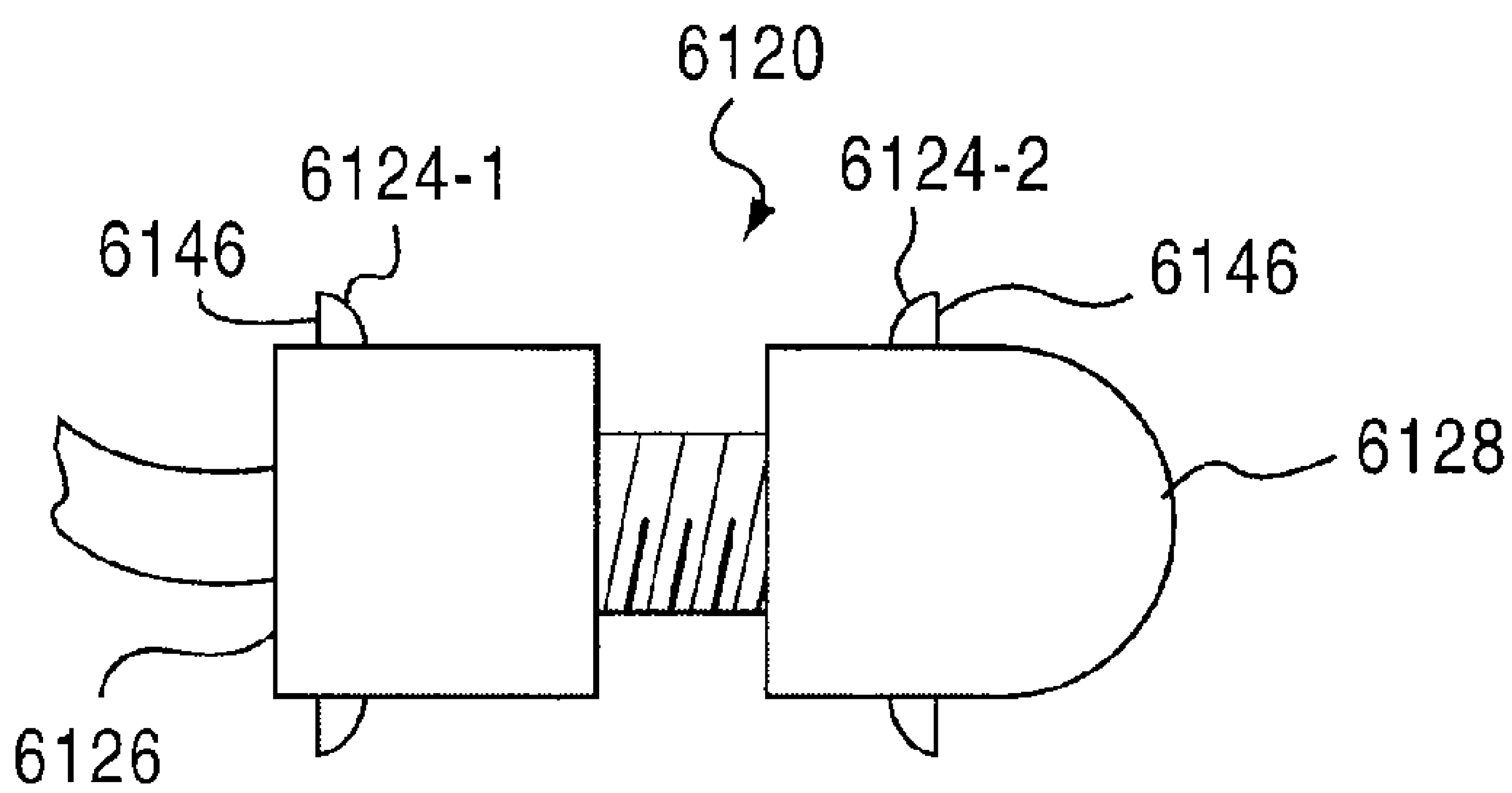


FIG.102

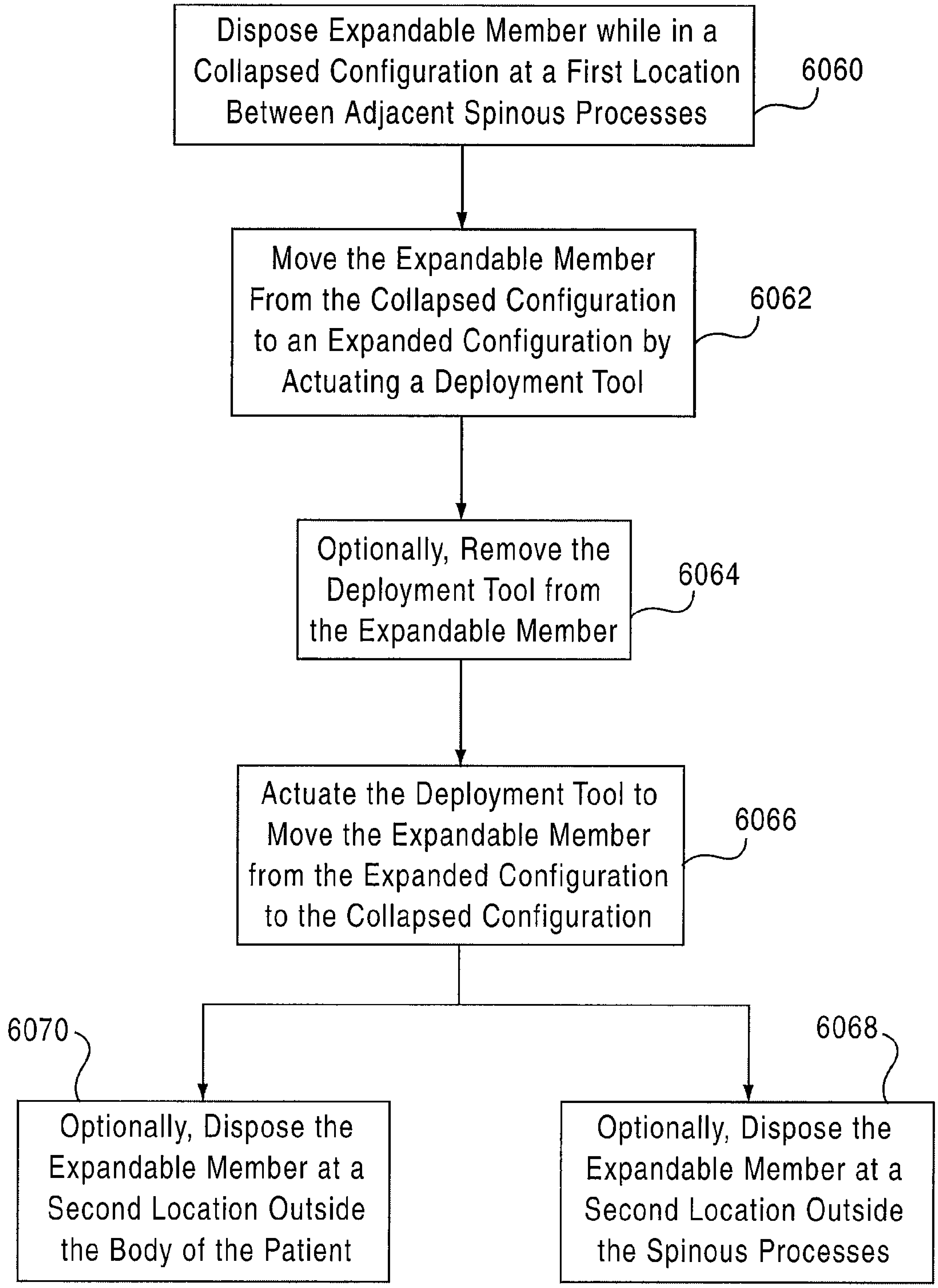

Dispose Expandable Member while in a Collapsed Configuration at a First Location Between Adjacent Spinous Processes
6060
Move the Expandable Member From the Collapsed Configuration to an Expanded Configuration by Actuating a Deployment Tool
6062
Optionally, Remove the Deployment Tool from the Expandable Member
6064
Actuate the Deployment Tool to Move the Expandable Member from the Expanded Configuration to the Collapsed Configuration
6066
6070
Optionally, Dispose the Expandable Member at a Second Location Outside the Body of the Patient
6068
Optionally, Dispose the Expandable Member at a Second Location Outside the Spinous Processes

FIG. 103

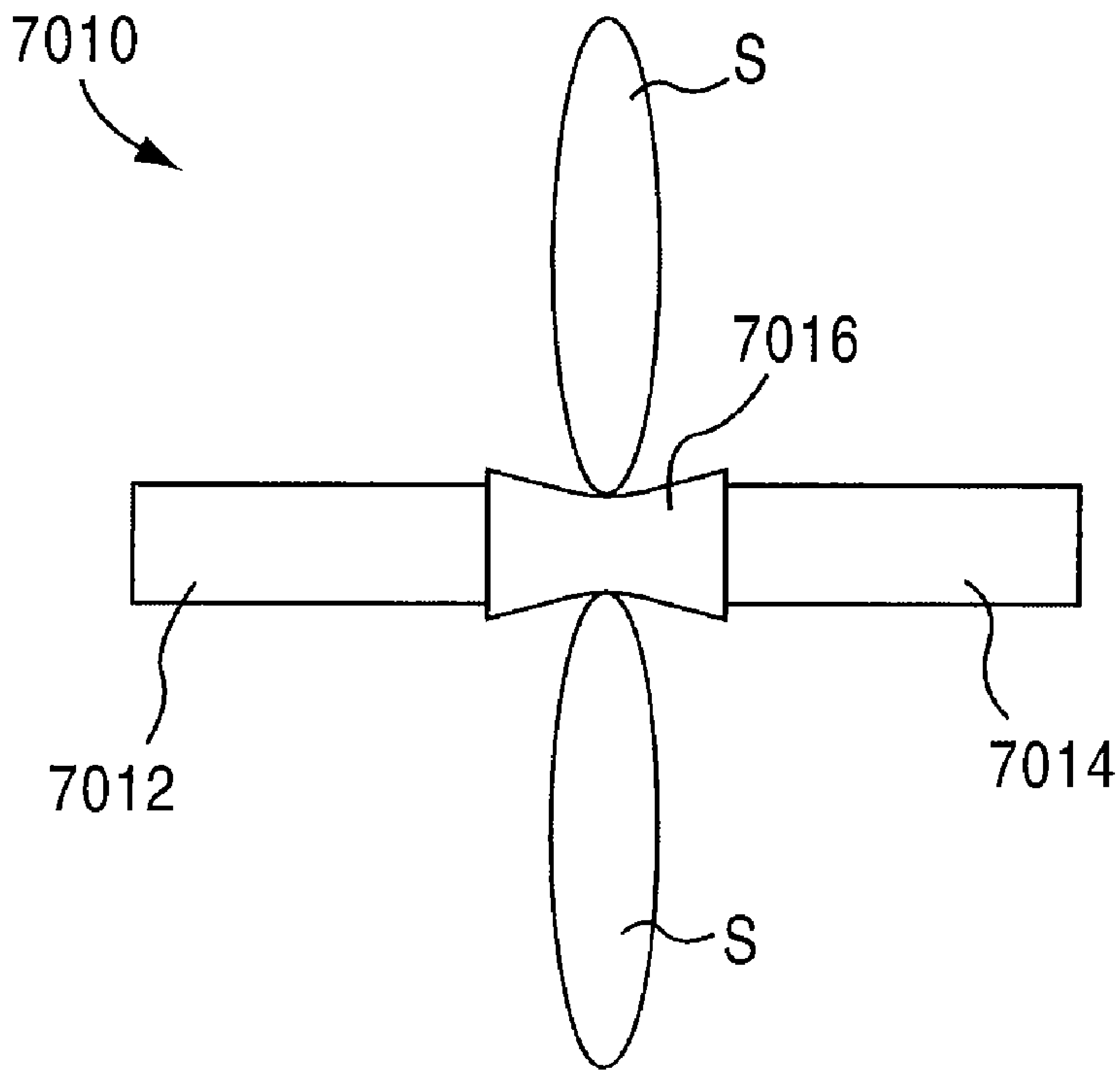


FIG.104

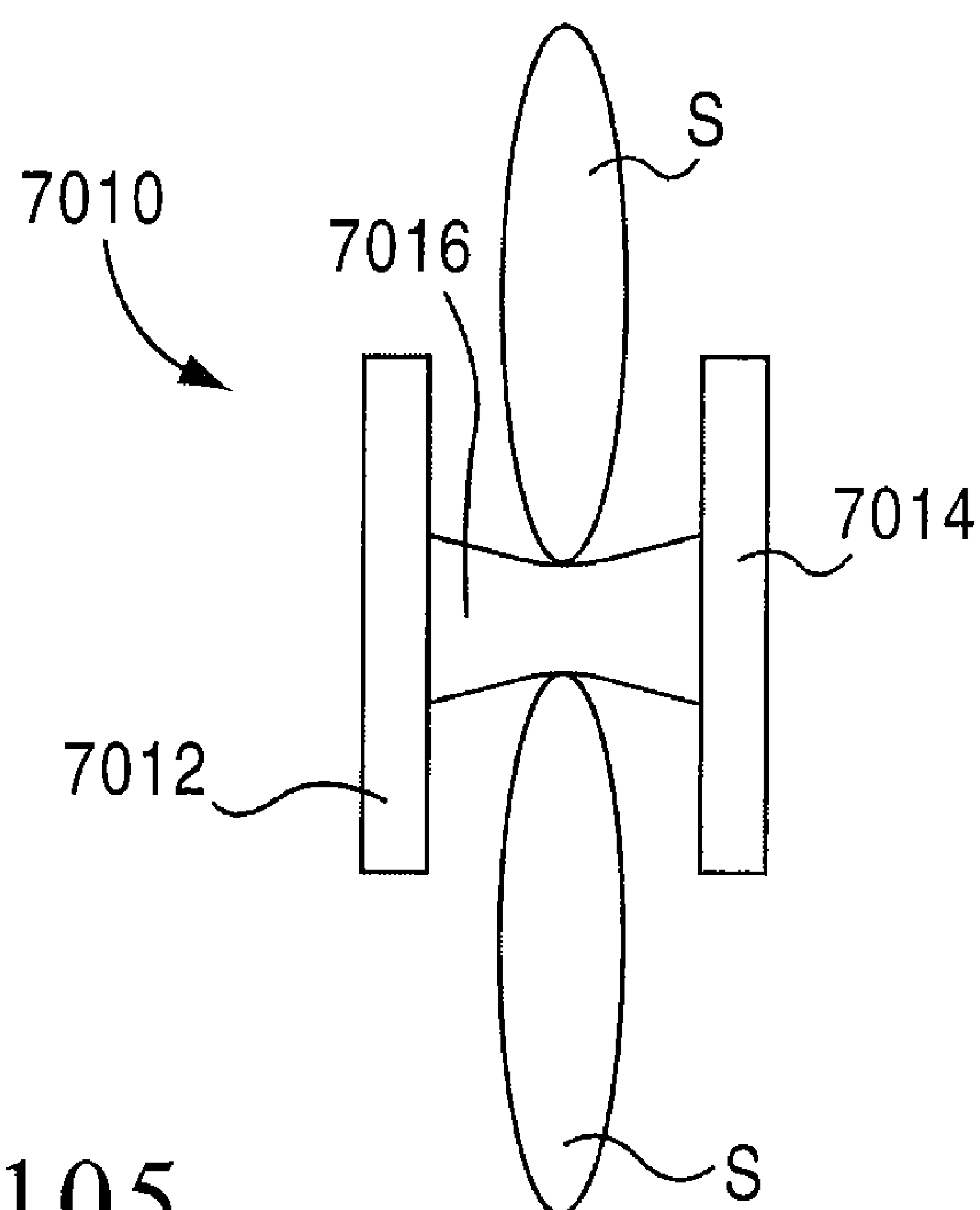


FIG.105

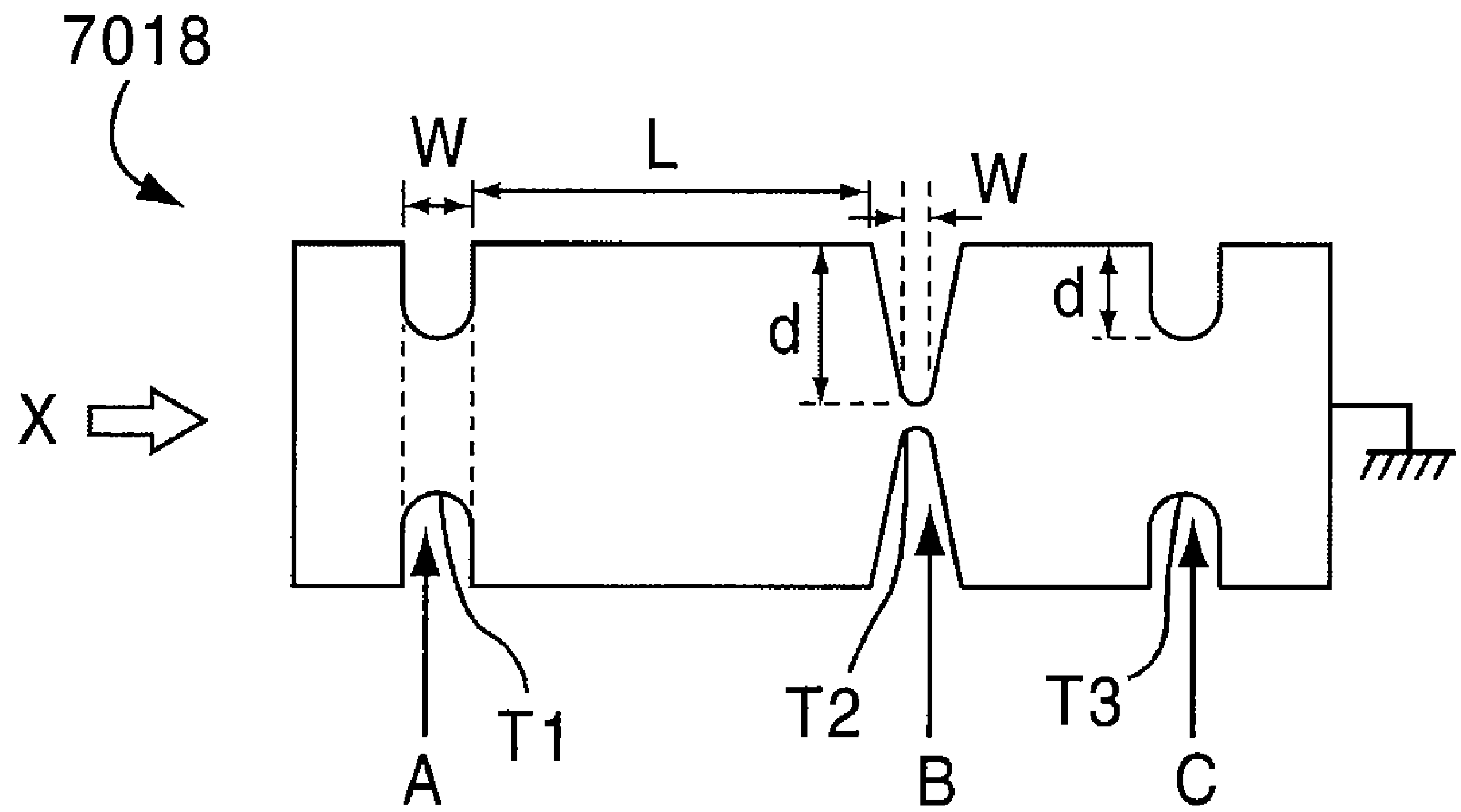


FIG.106

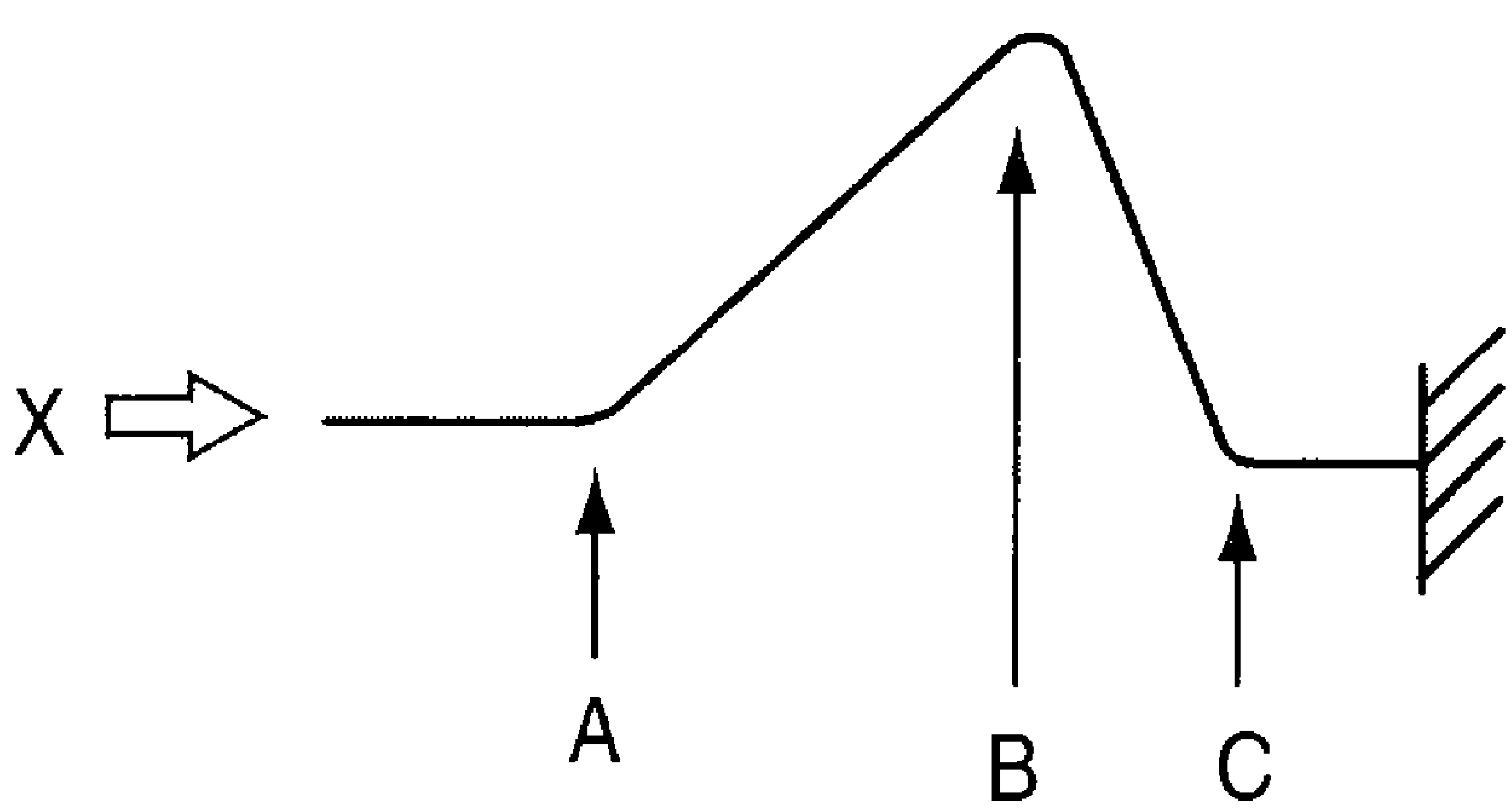


FIG.107

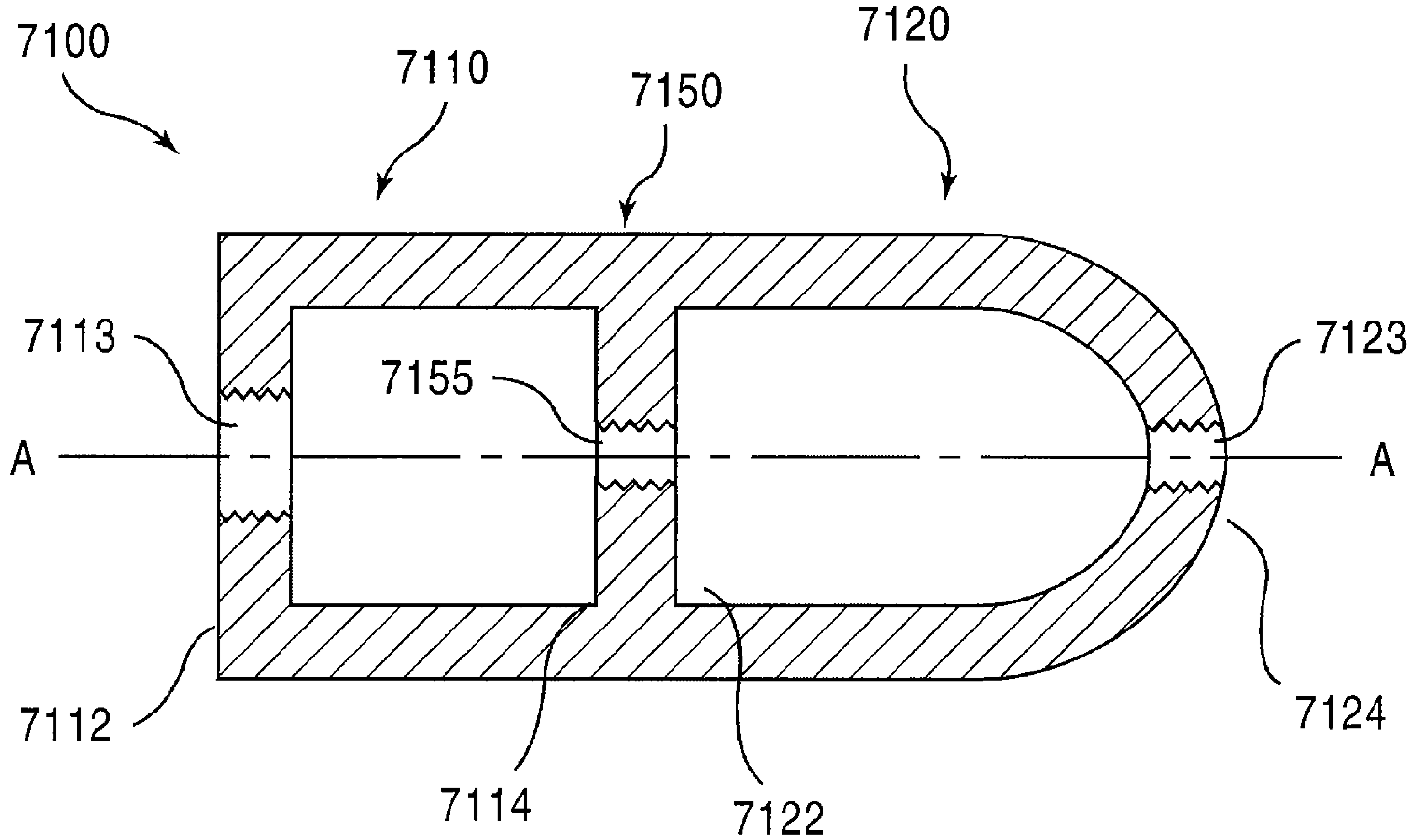


FIG.108

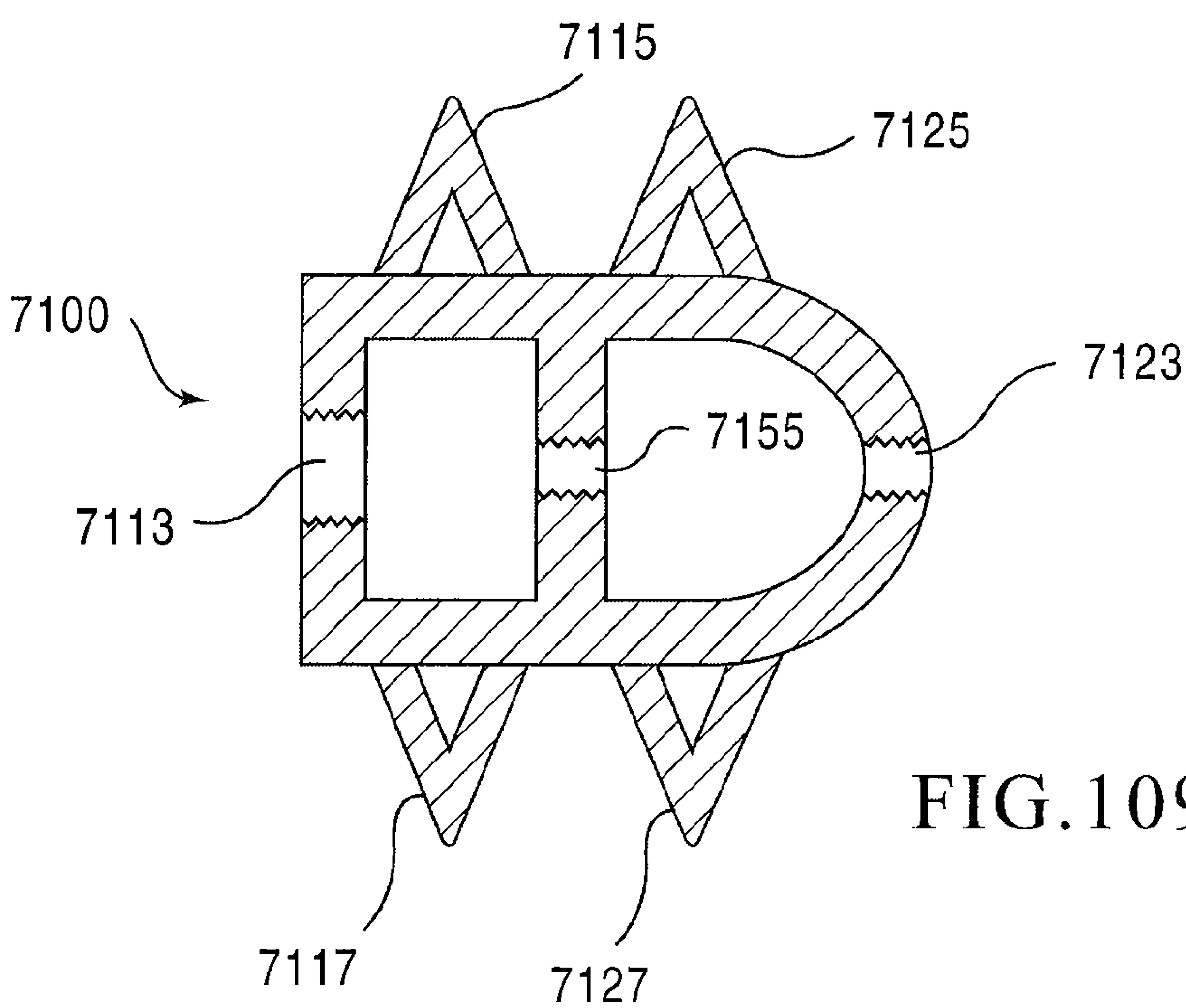


FIG.109

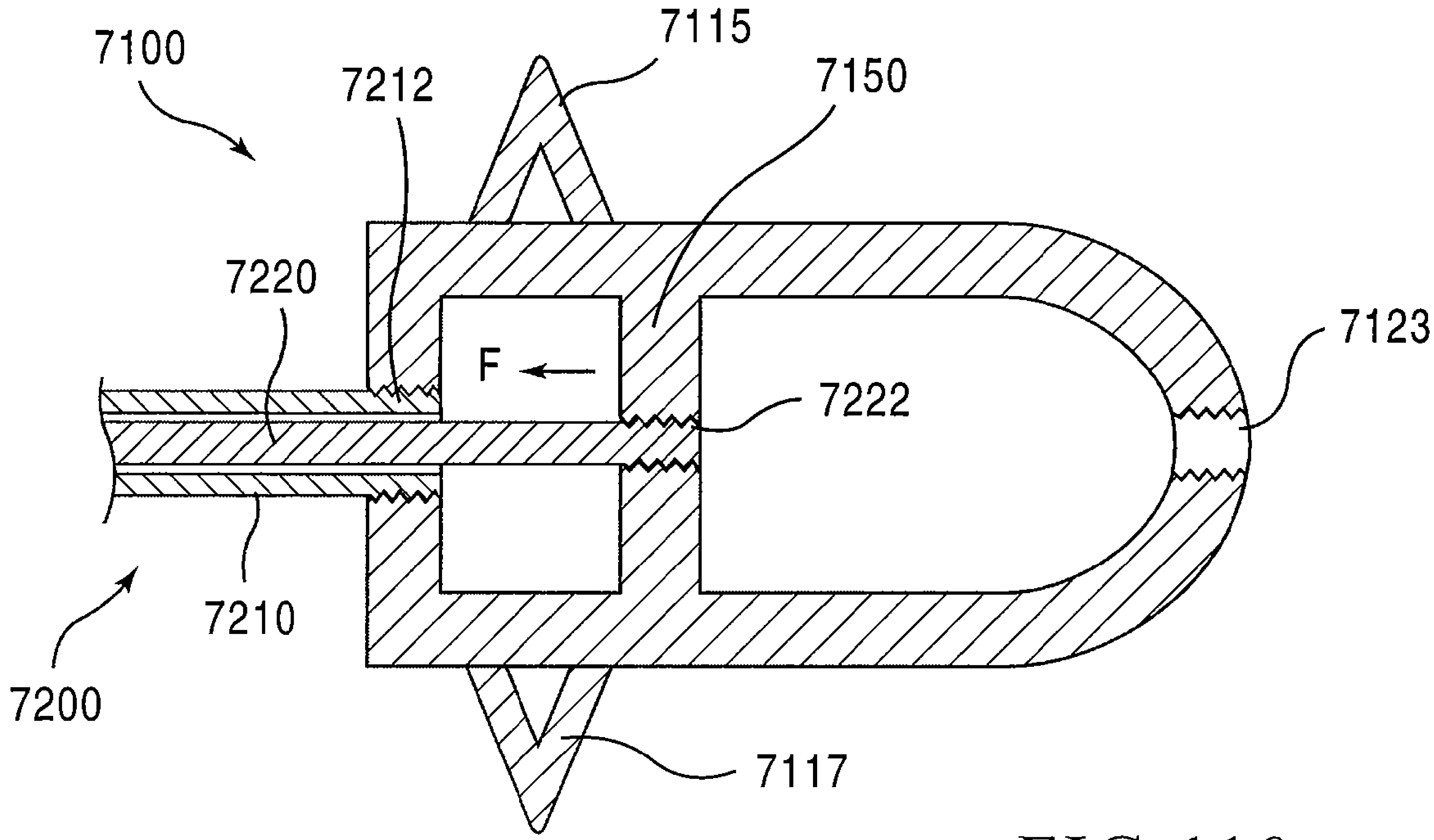


FIG. 110

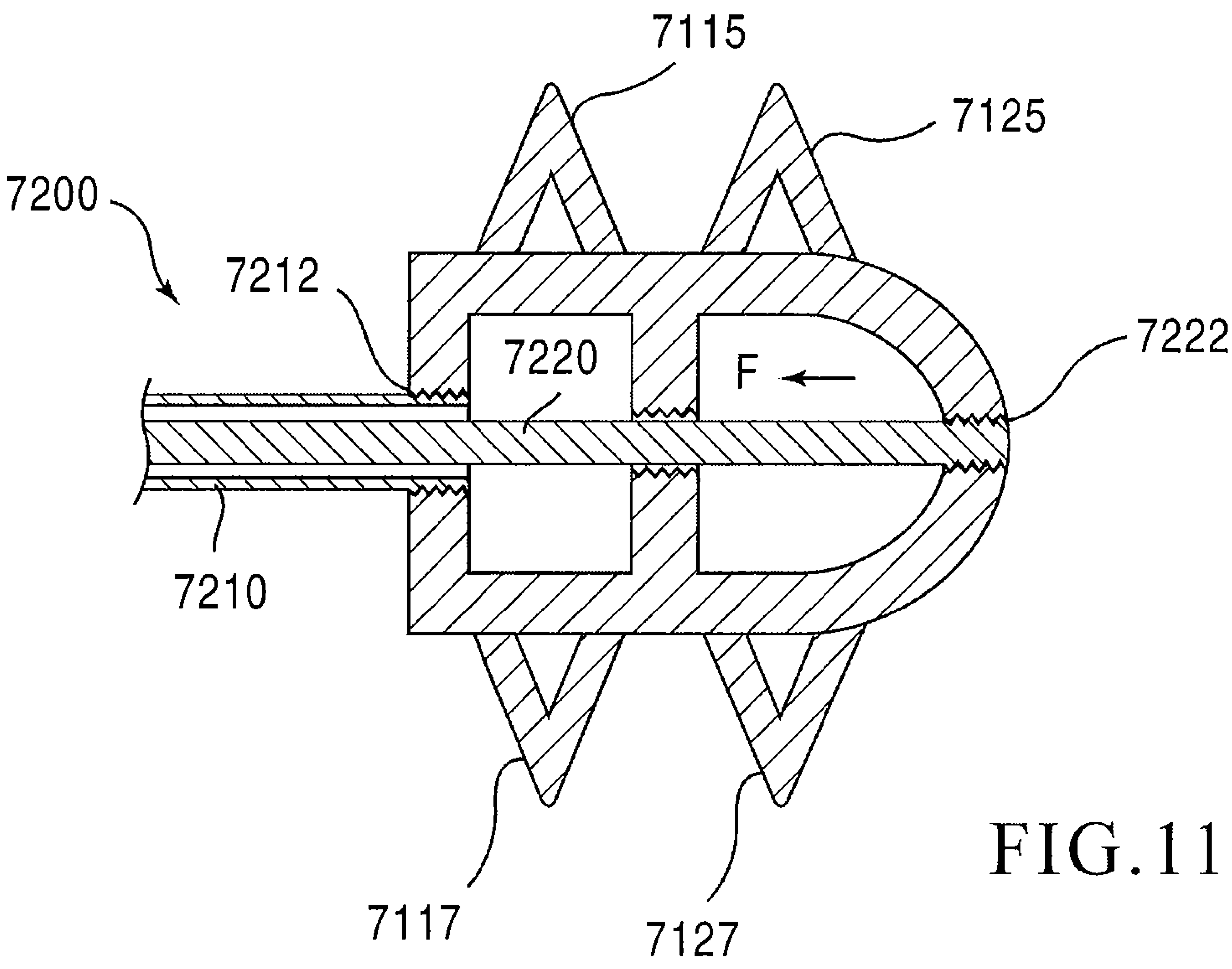


FIG. 111

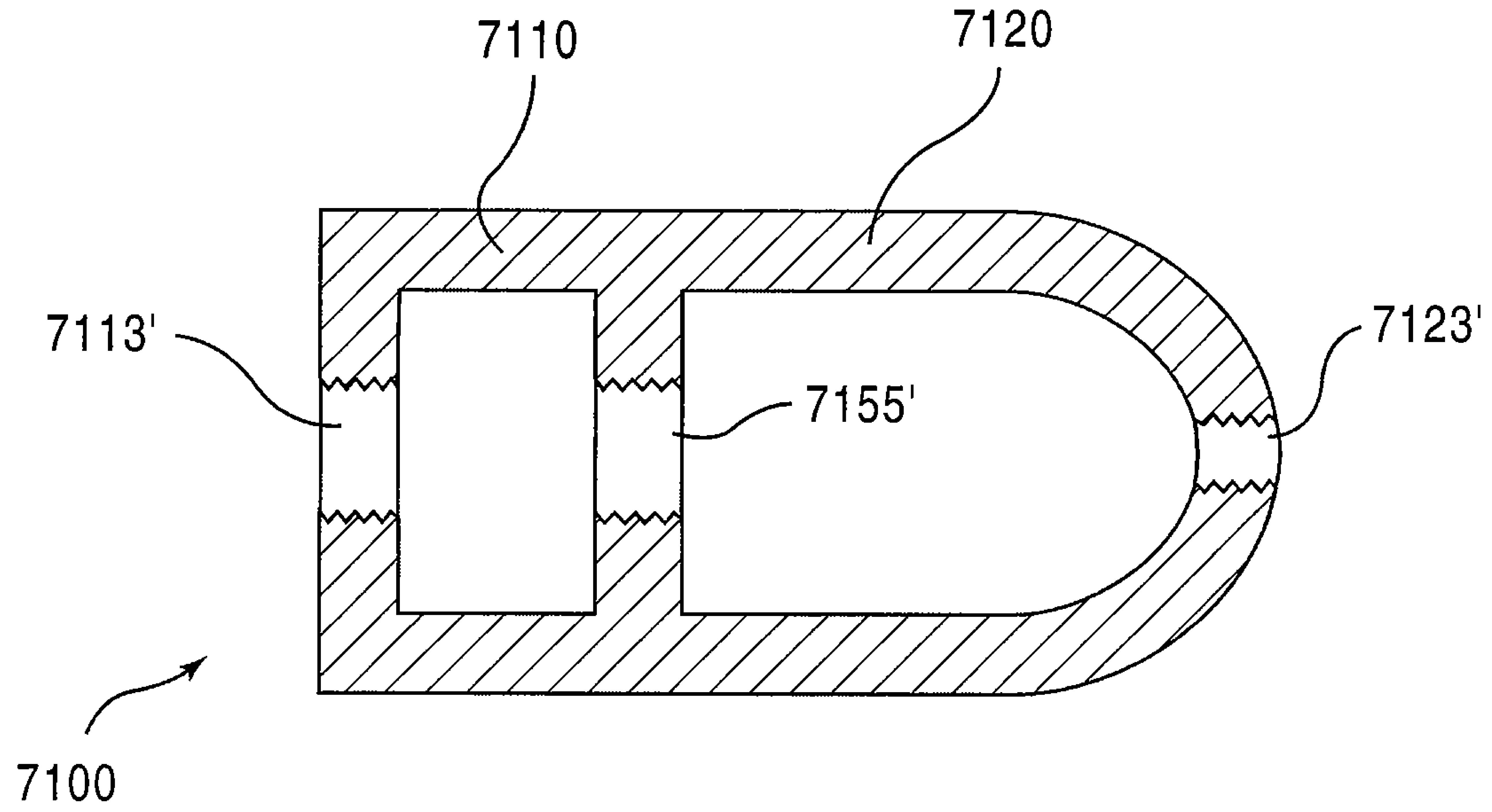


FIG.112

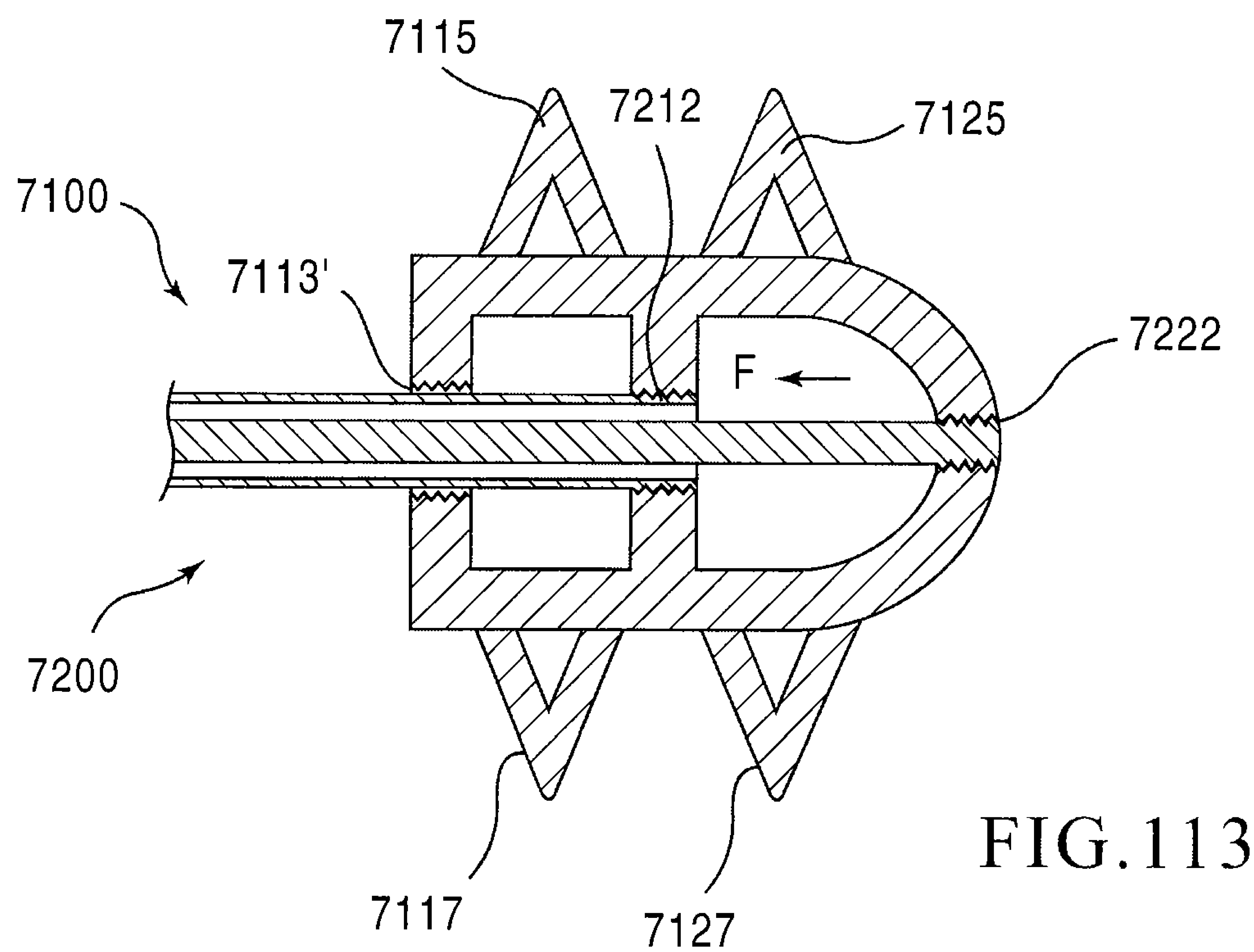


FIG.113

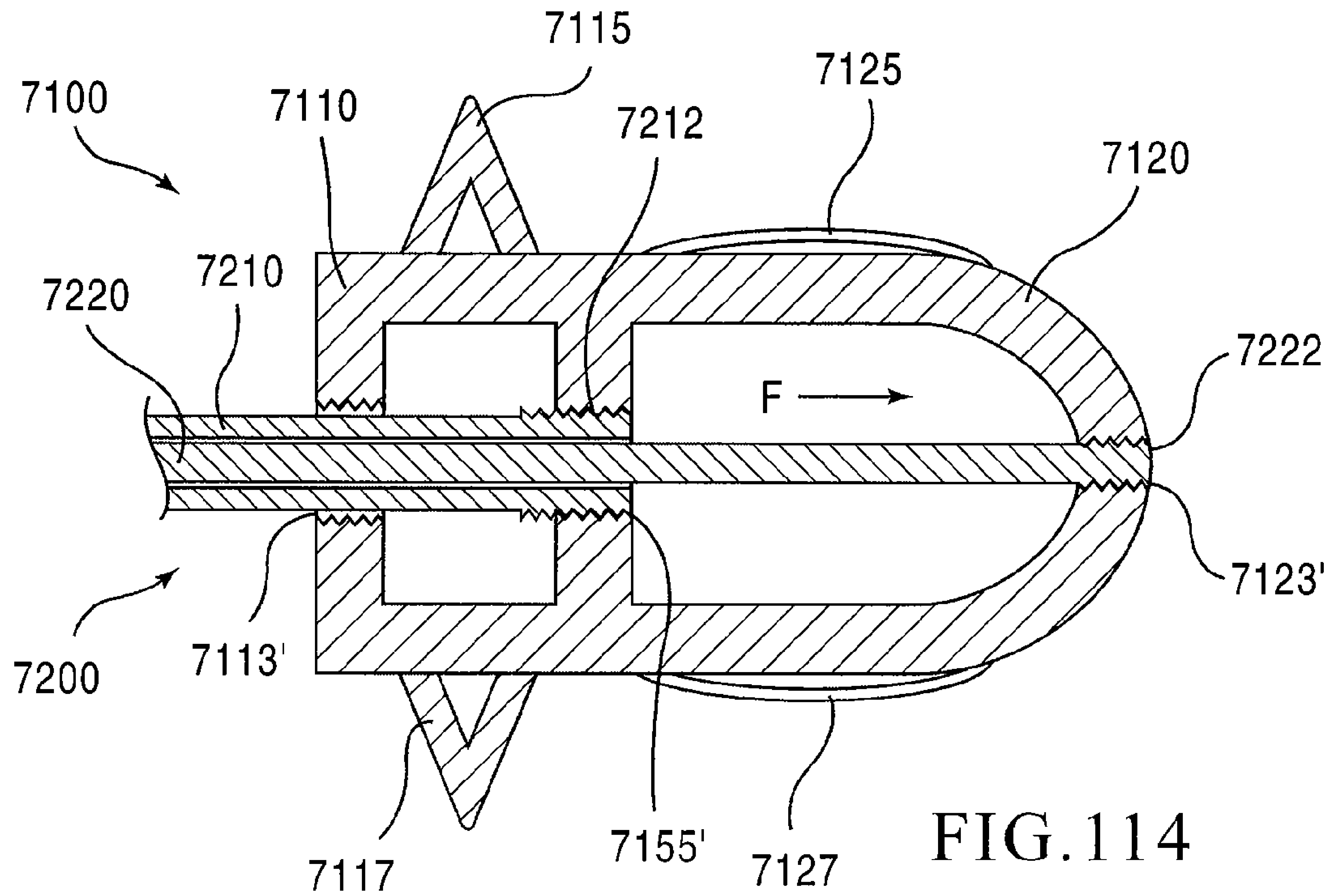


FIG.114

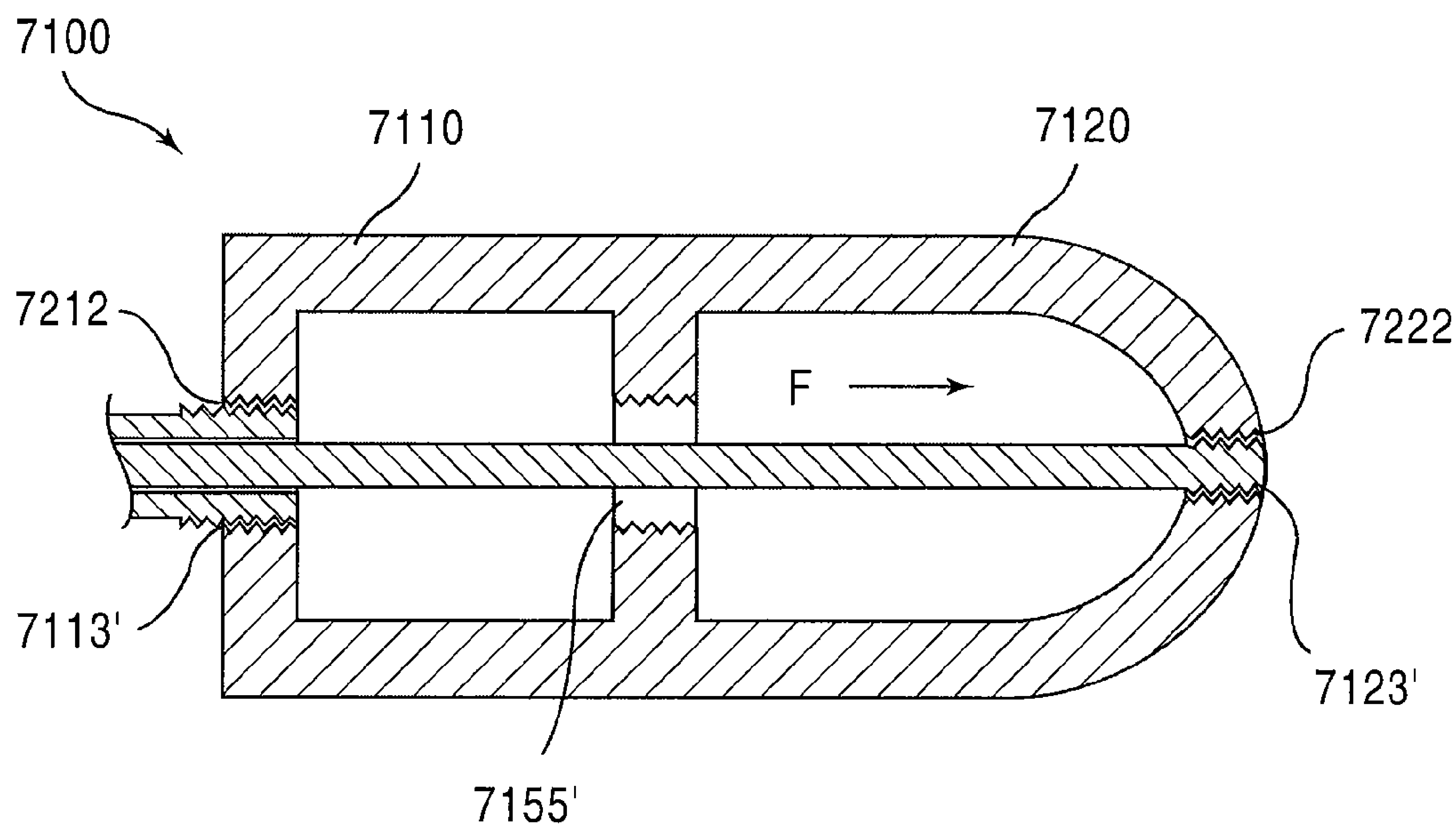


FIG.115

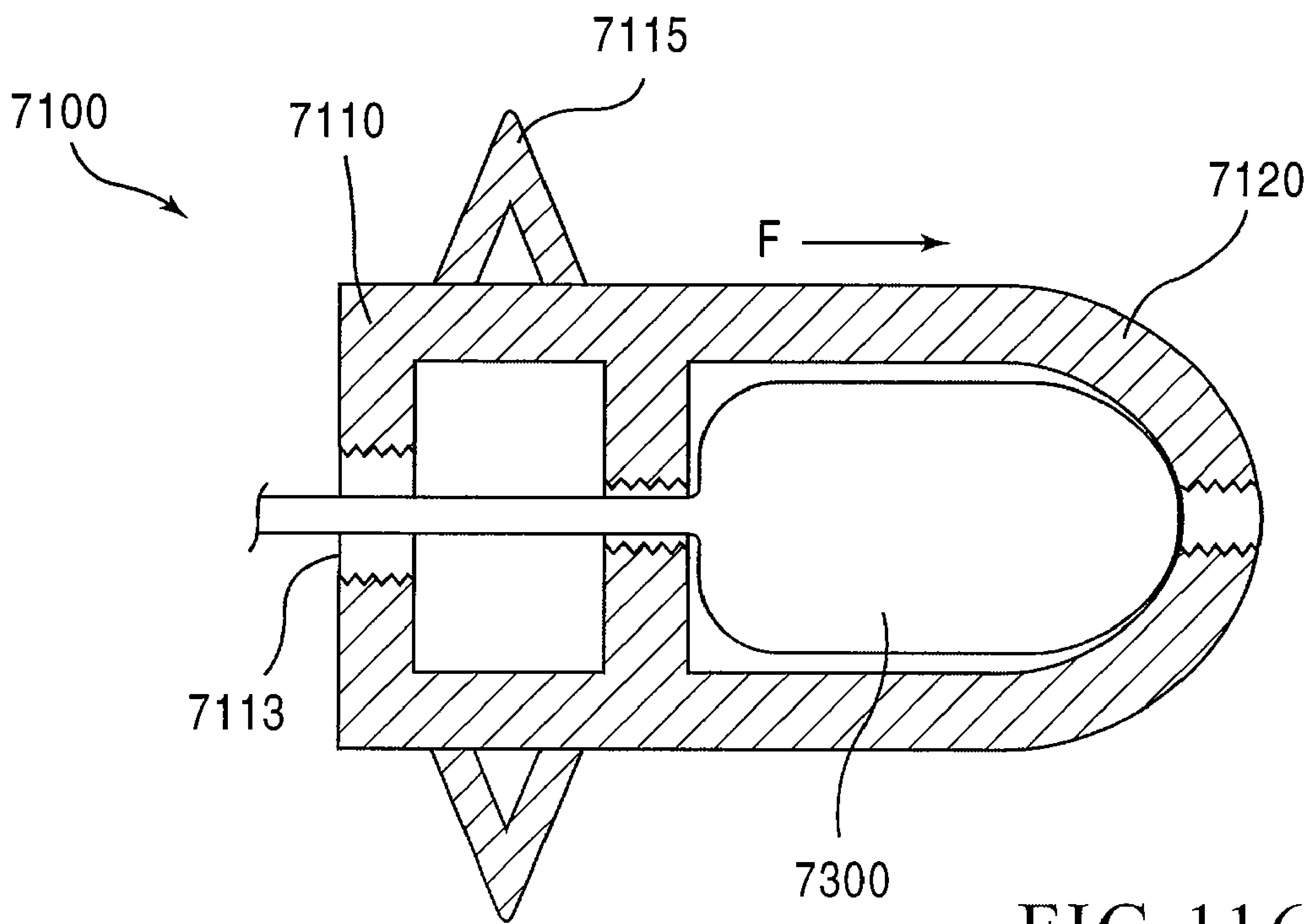


FIG.116

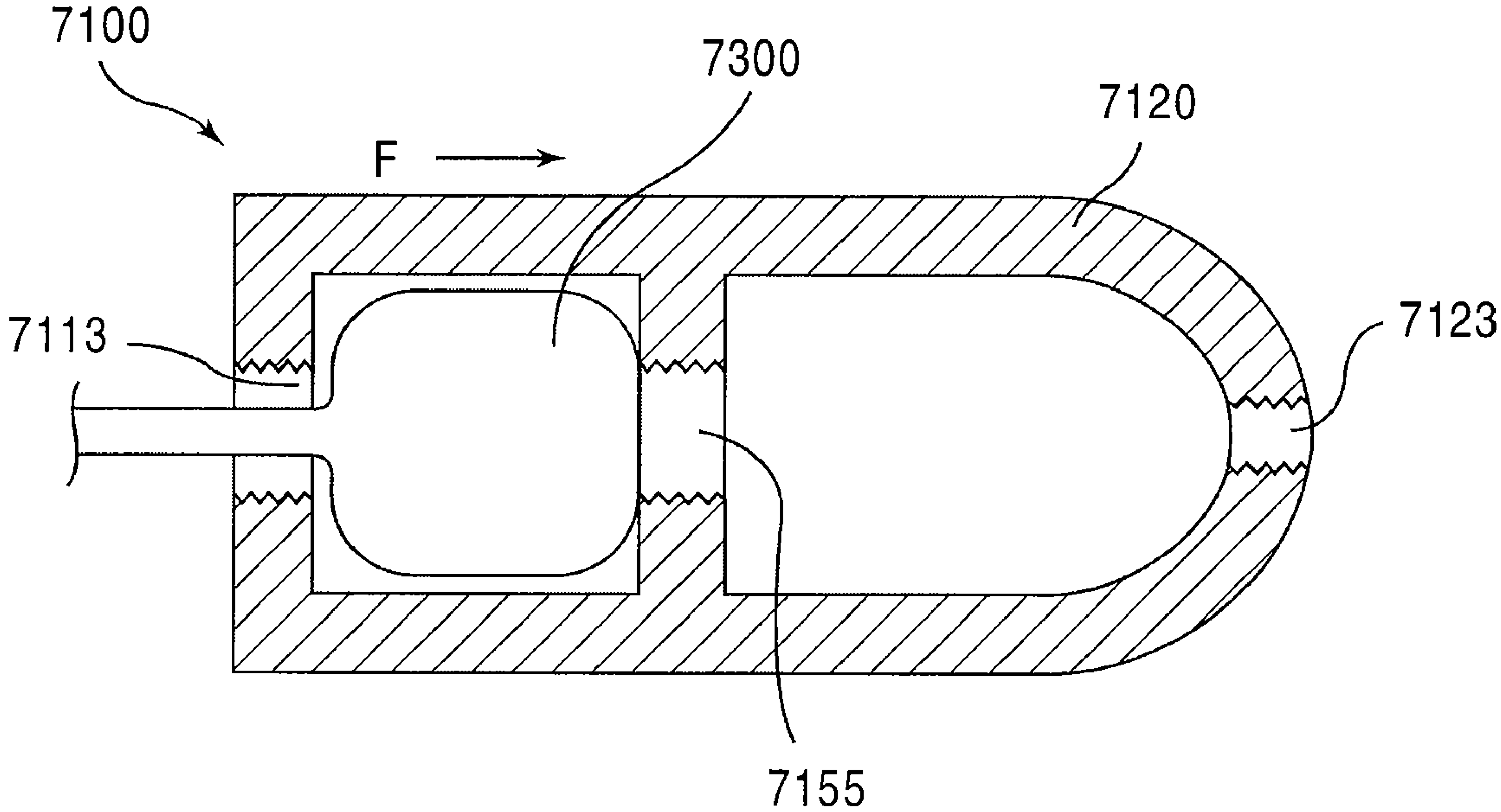


FIG.117

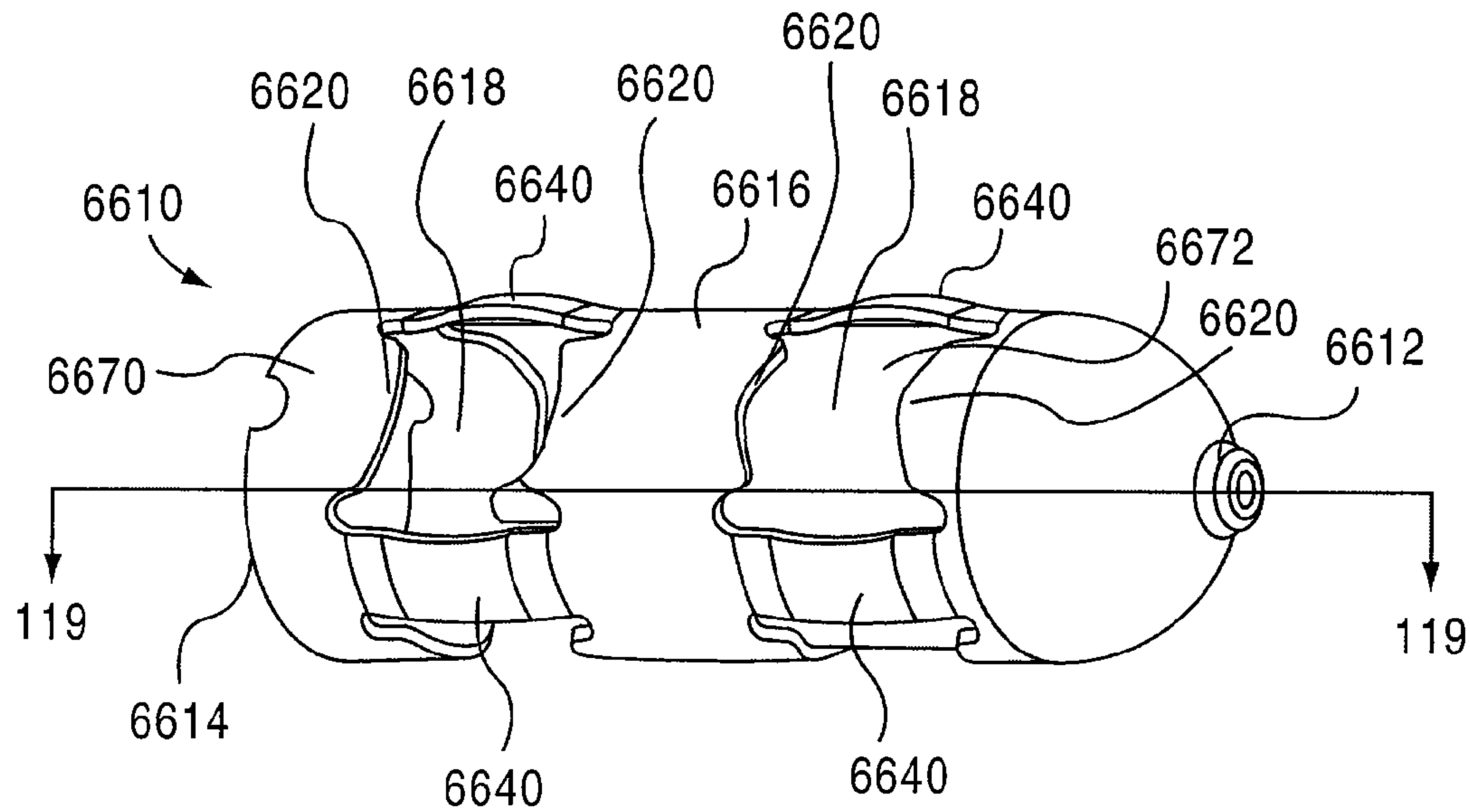


FIG.118

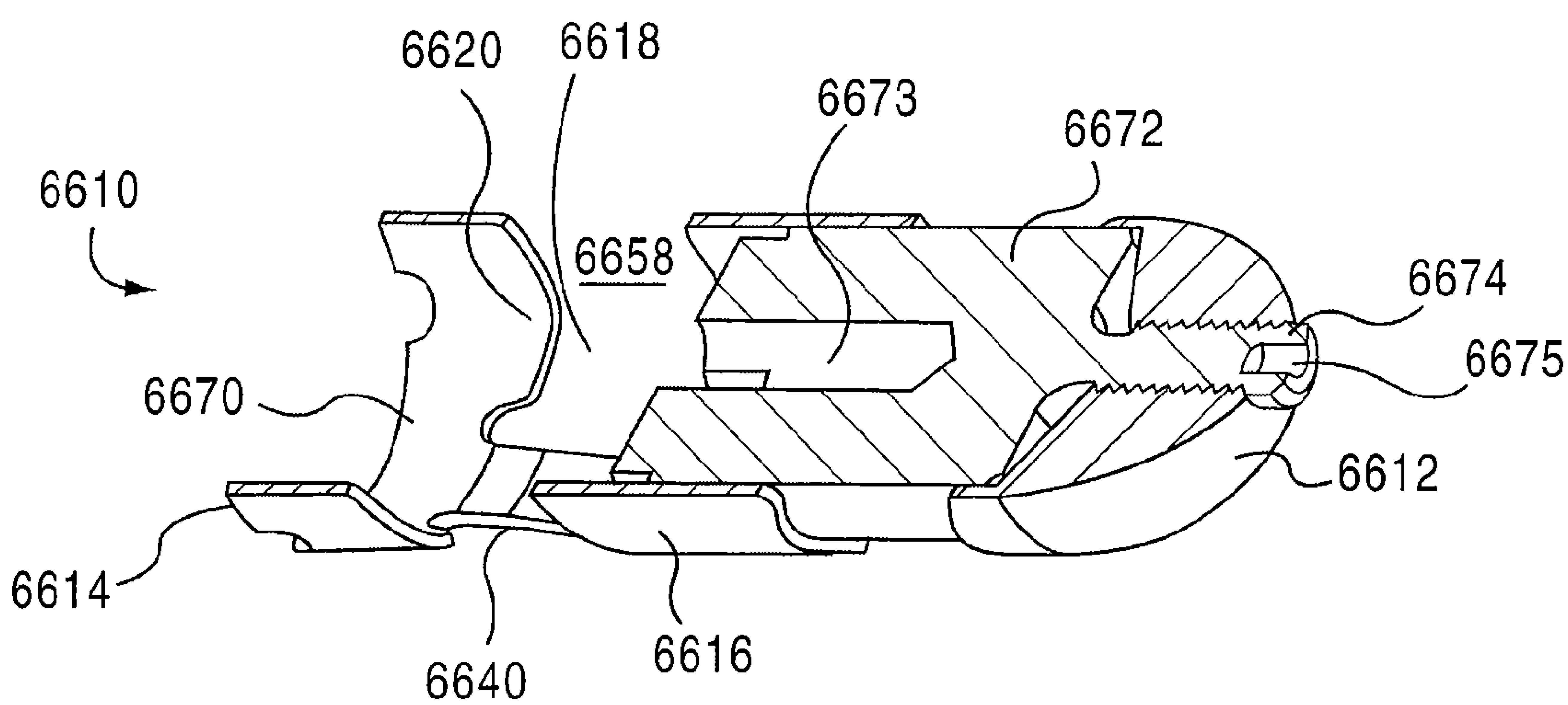


FIG.119

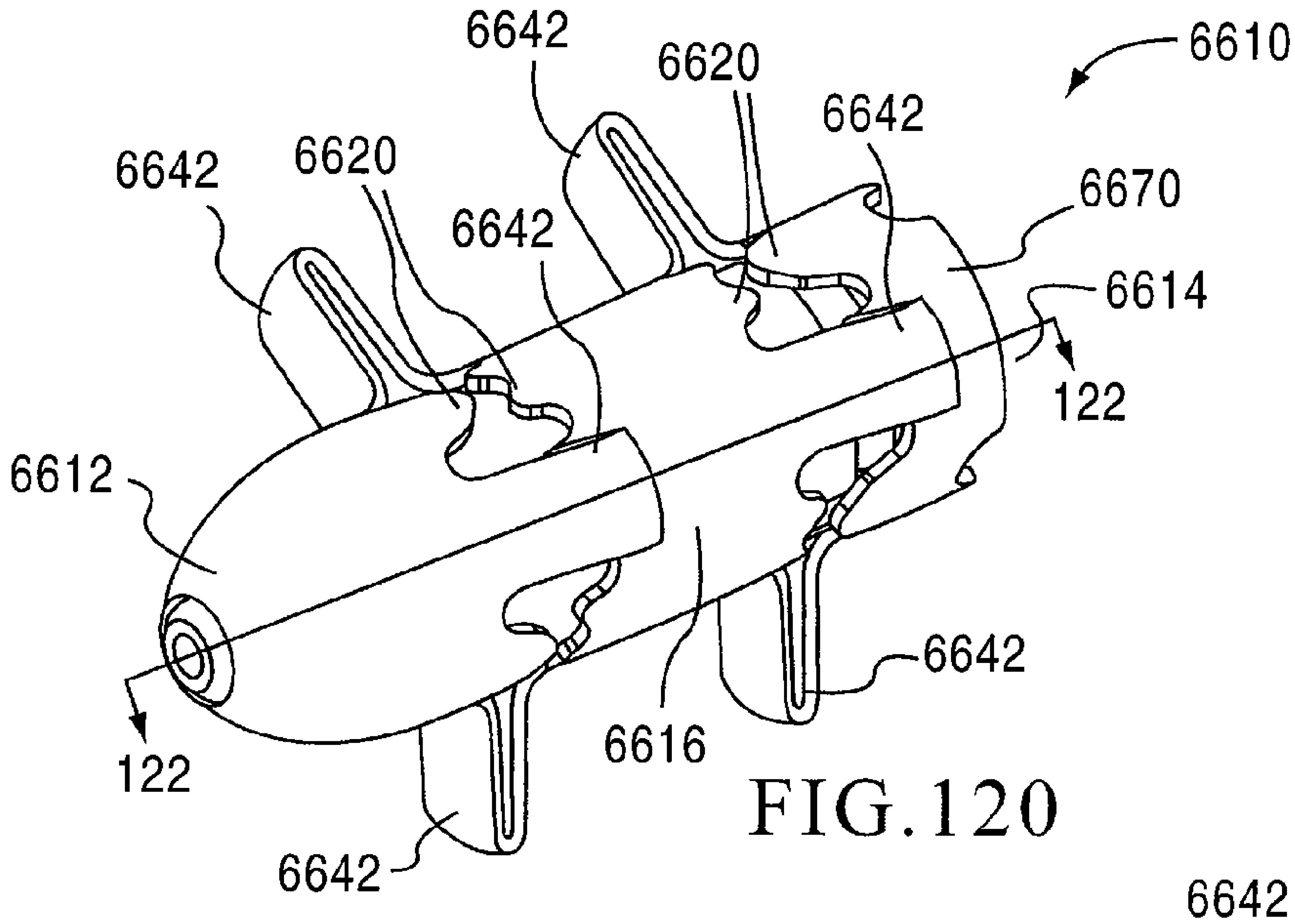


FIG.120

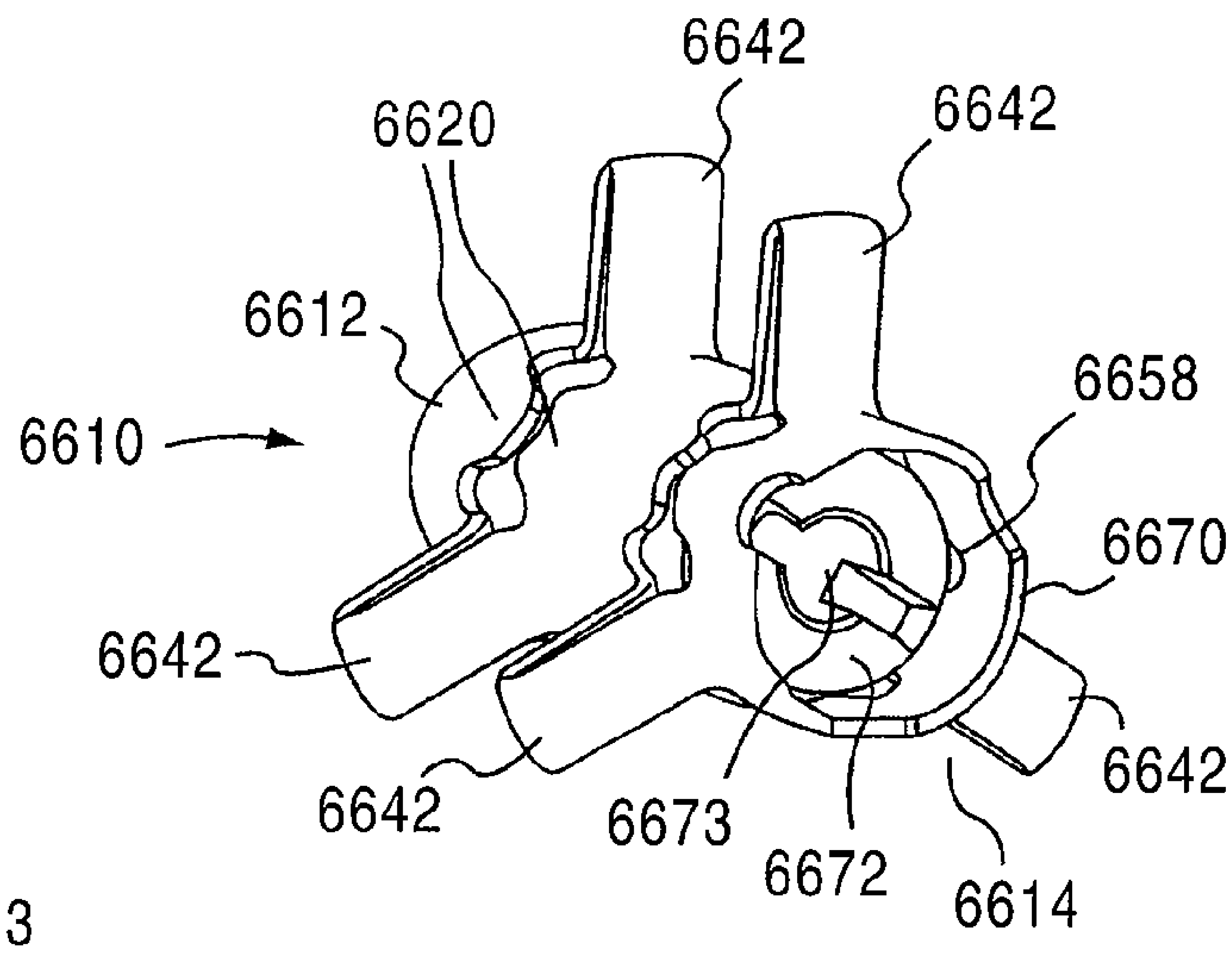


FIG.121

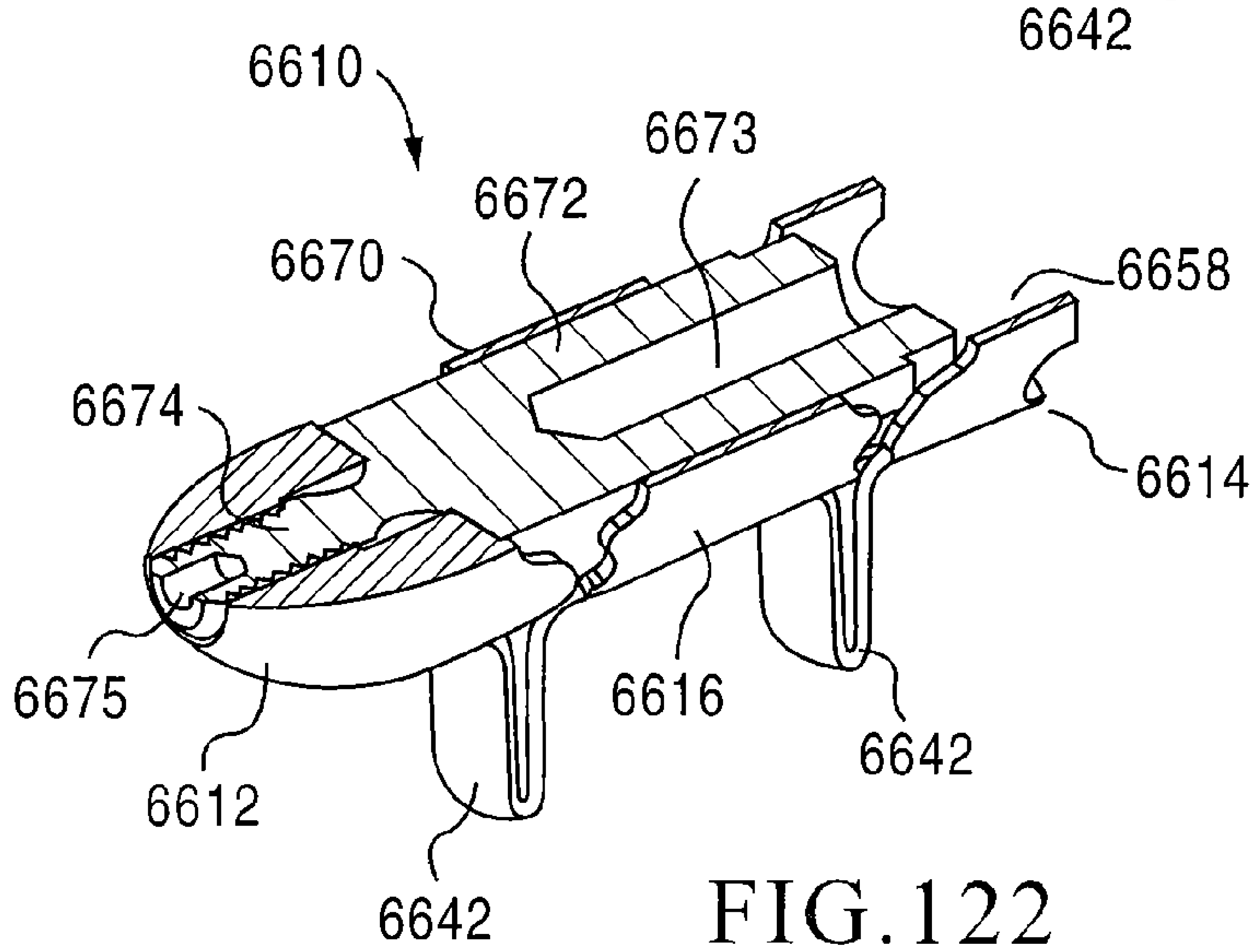


FIG.122

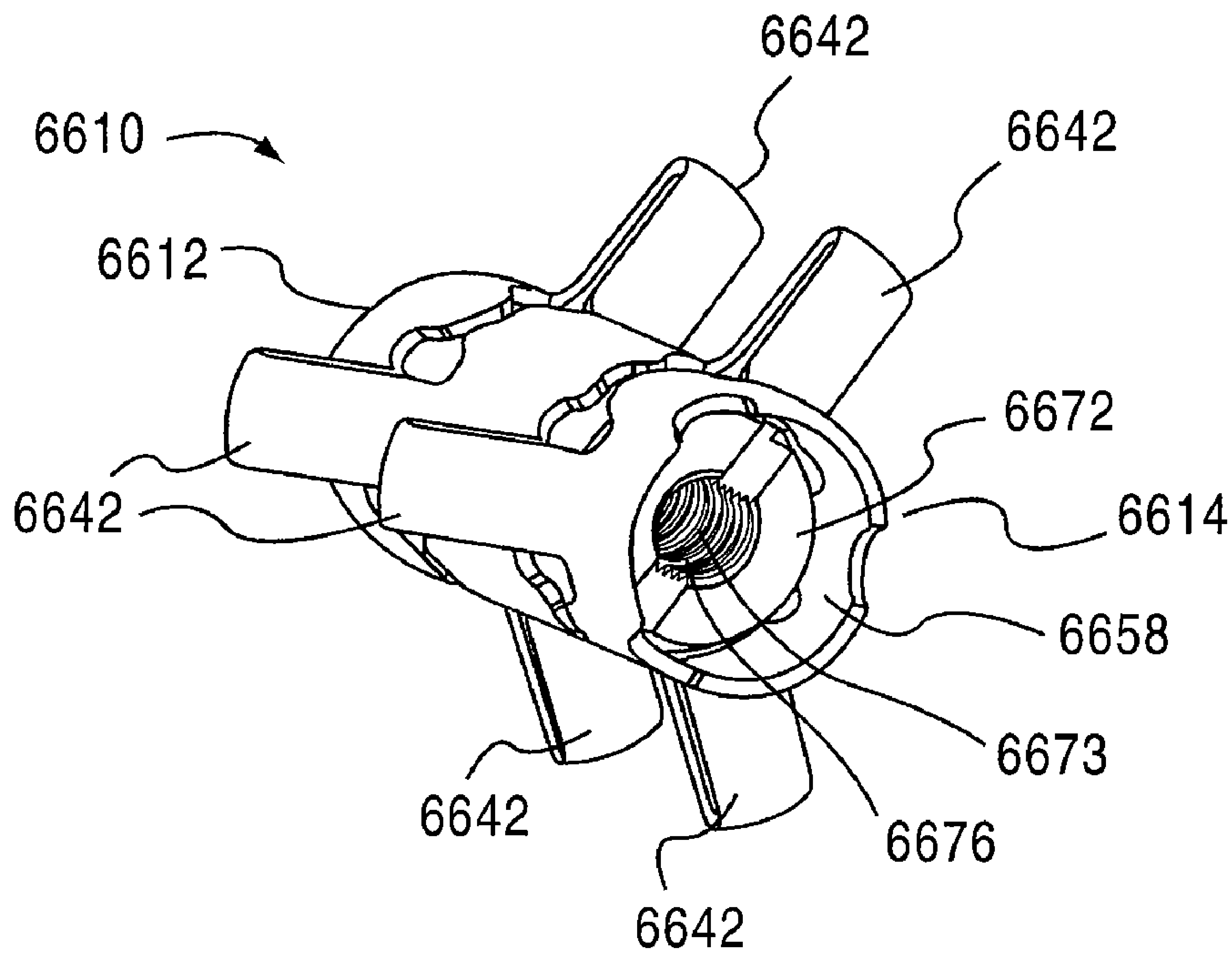


FIG.123

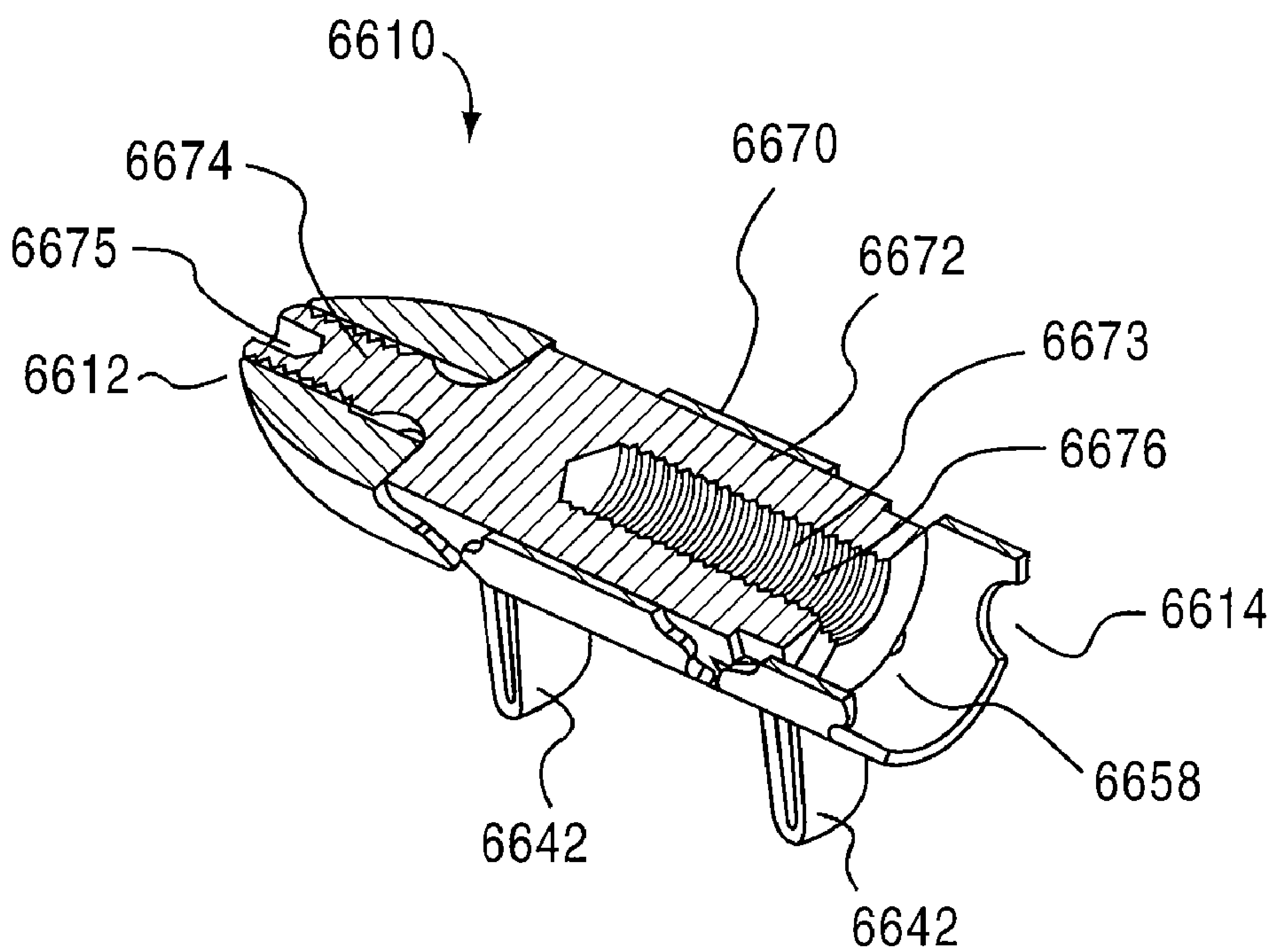


FIG.124

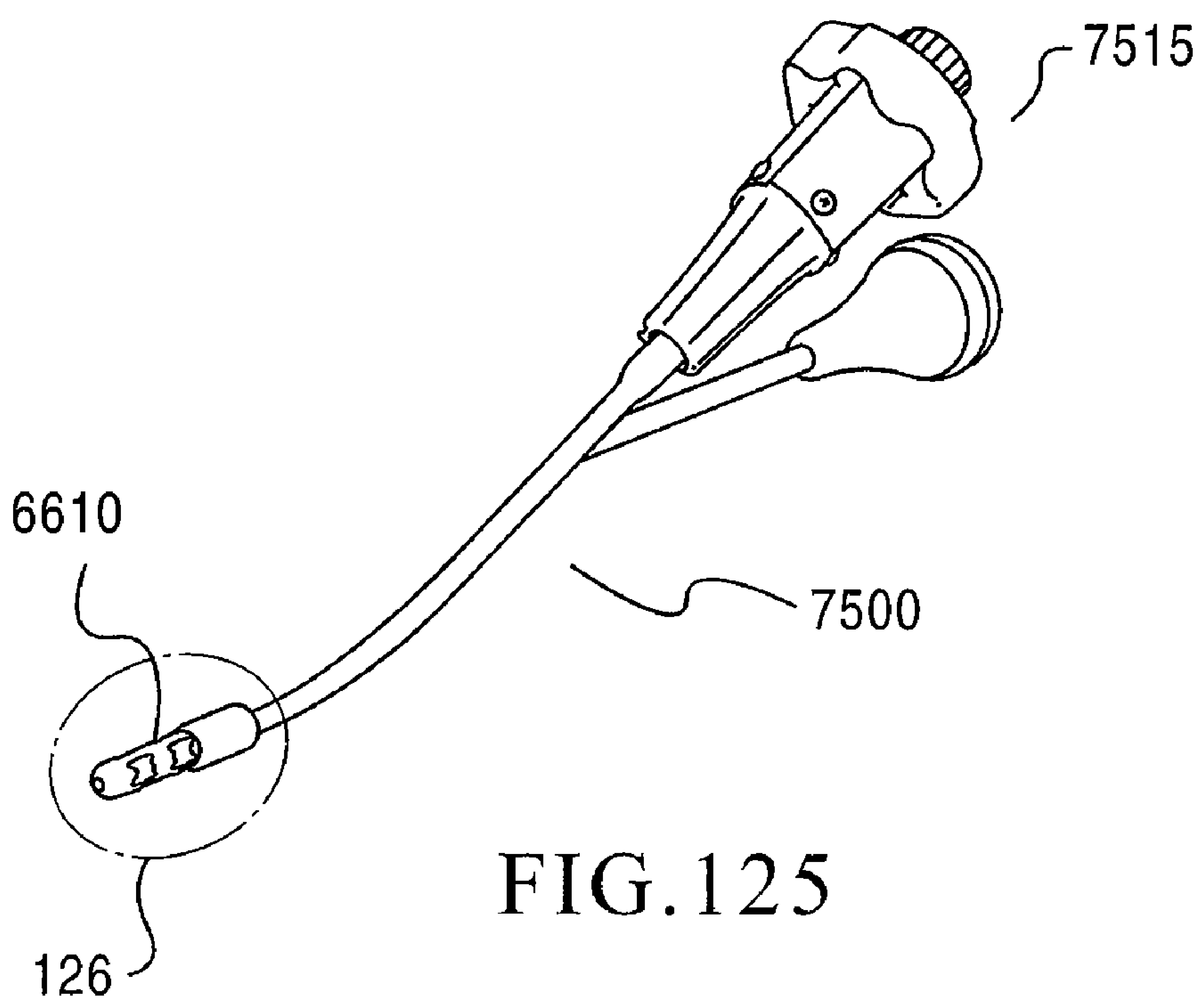


FIG.125

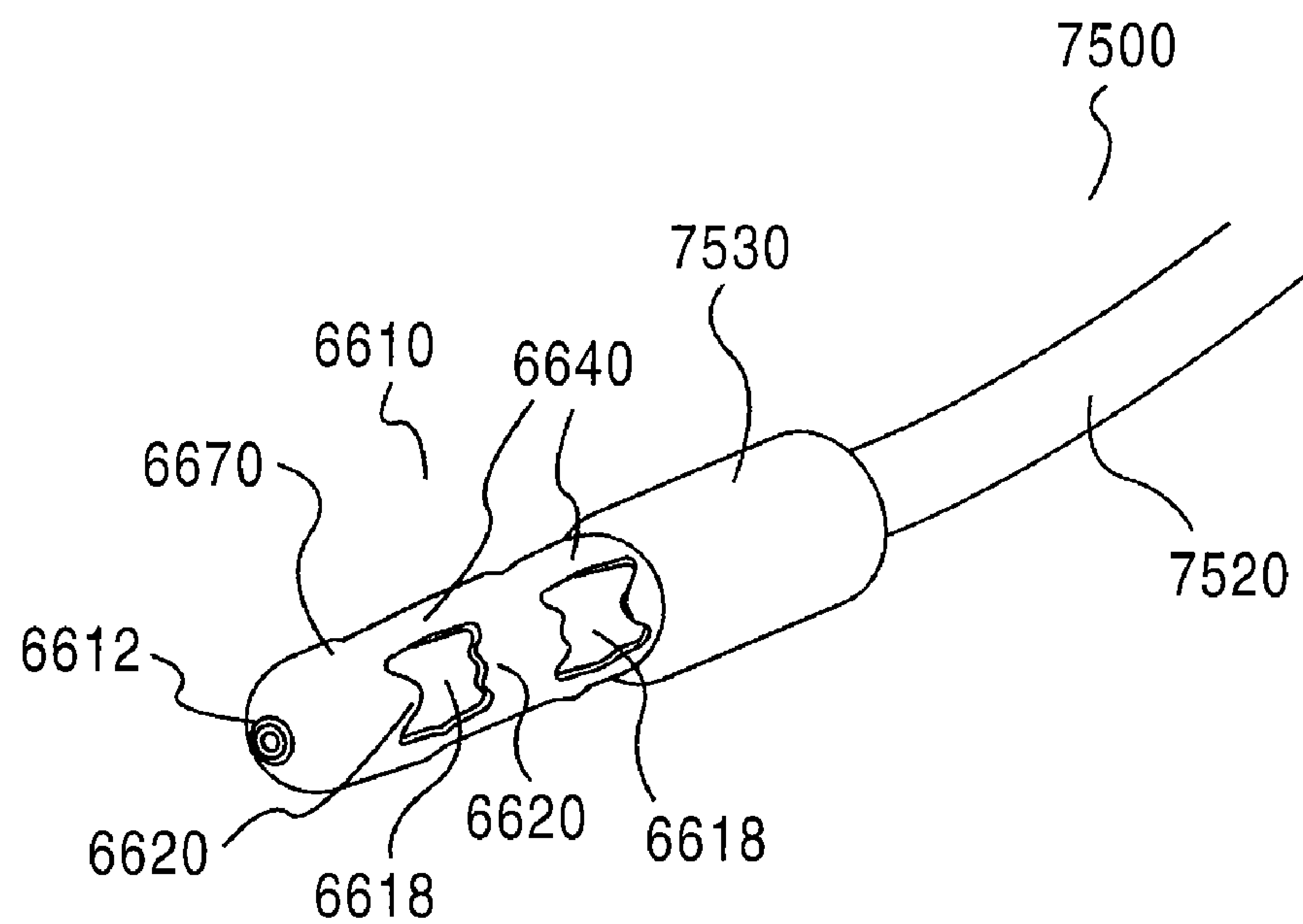


FIG.126

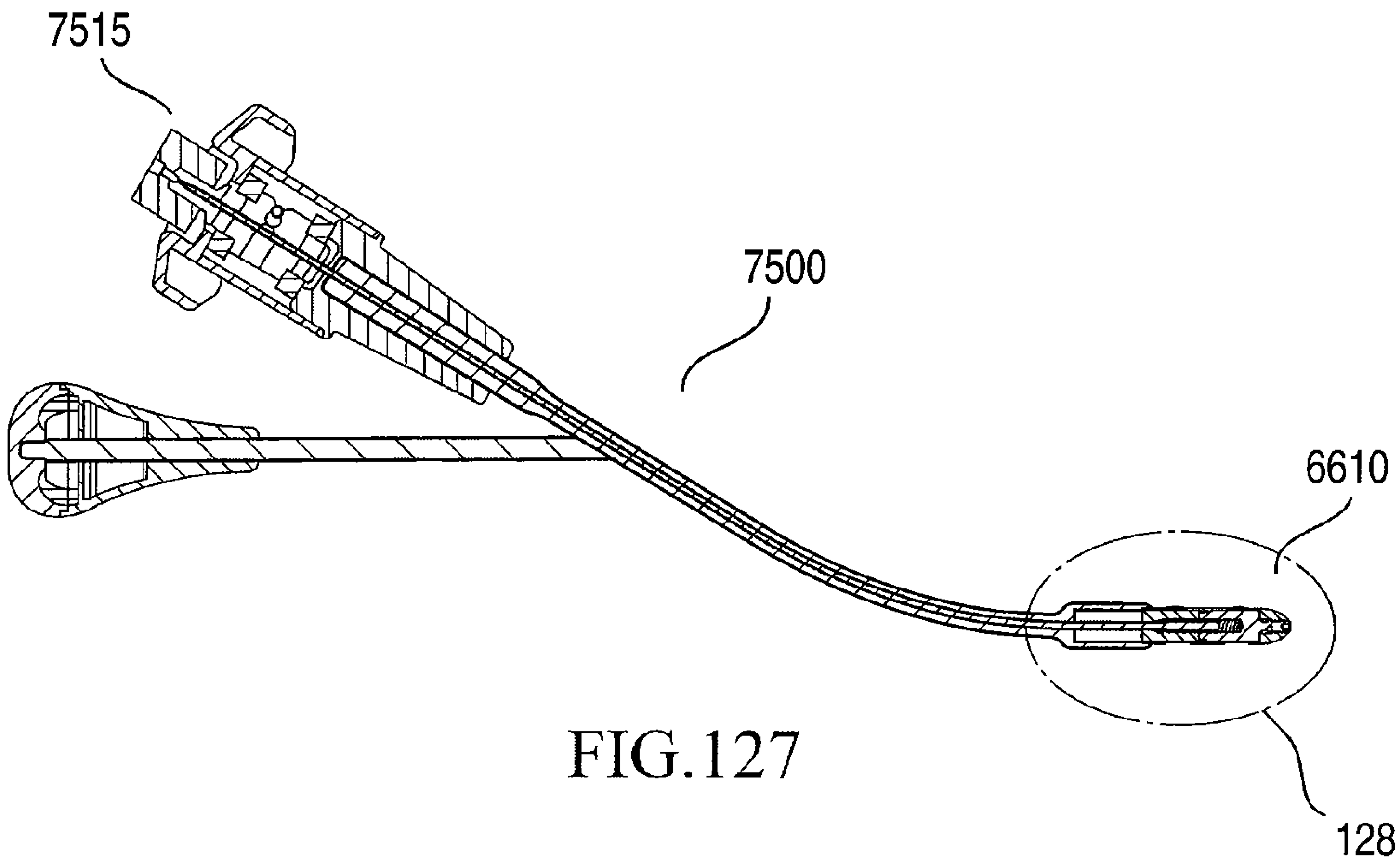


FIG.127

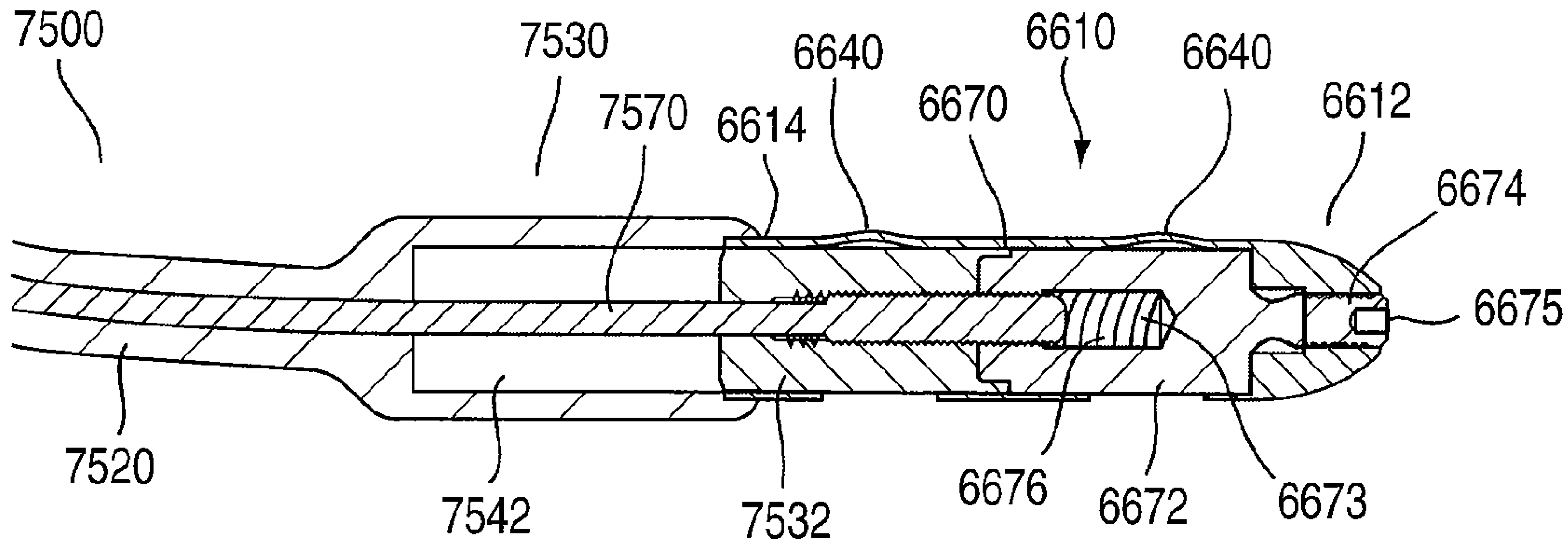


FIG.128

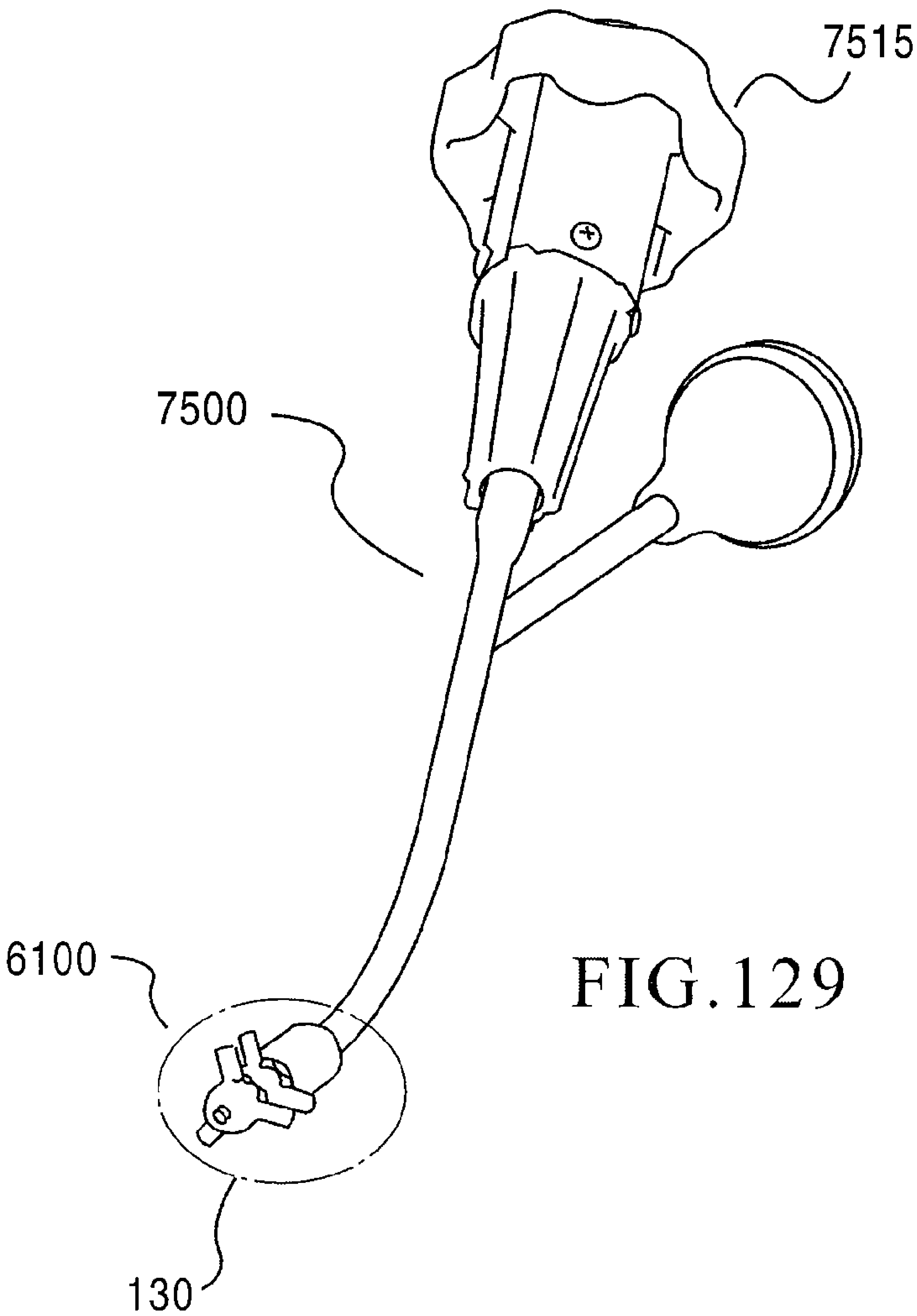


FIG.129

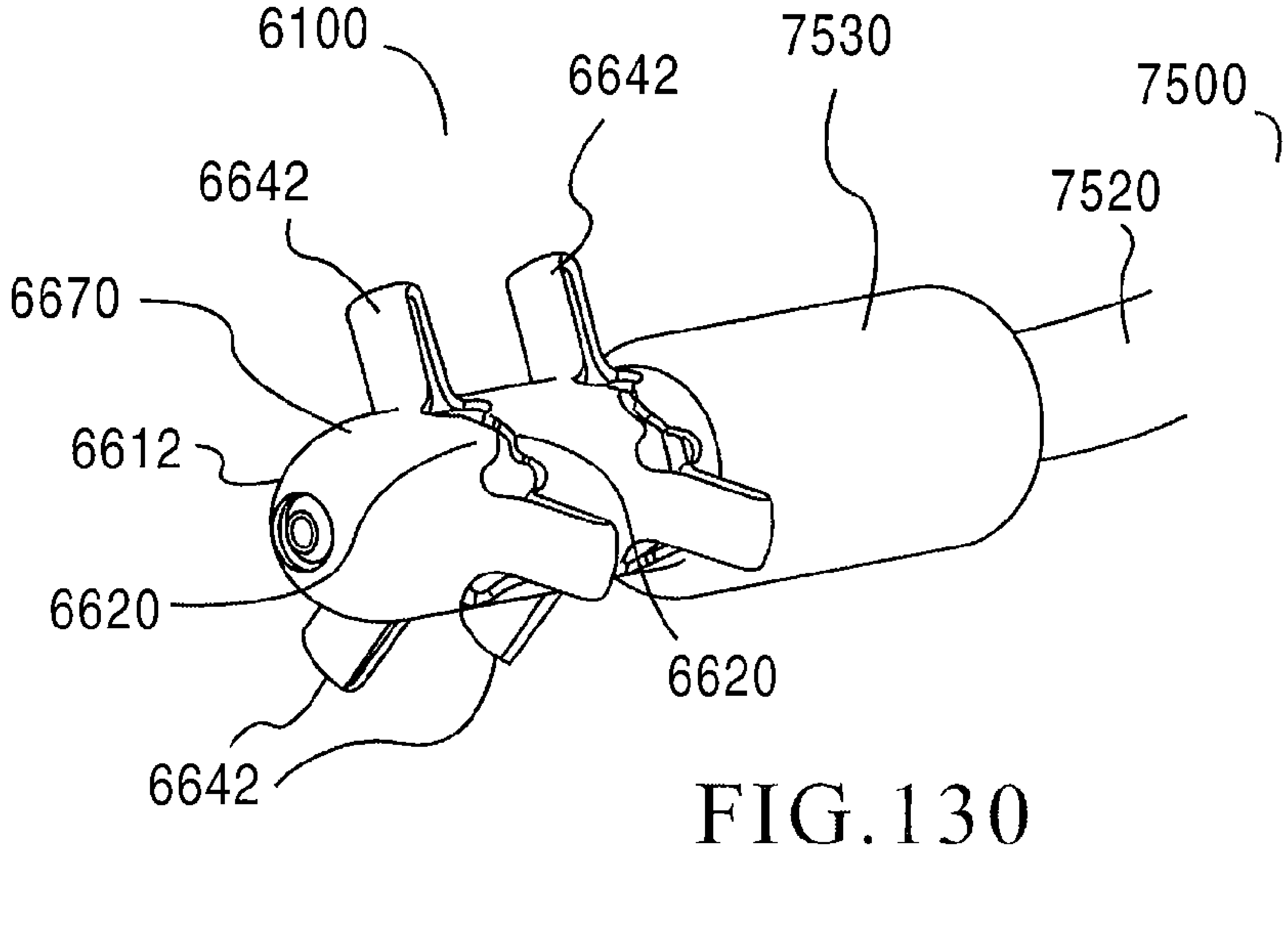


FIG.130

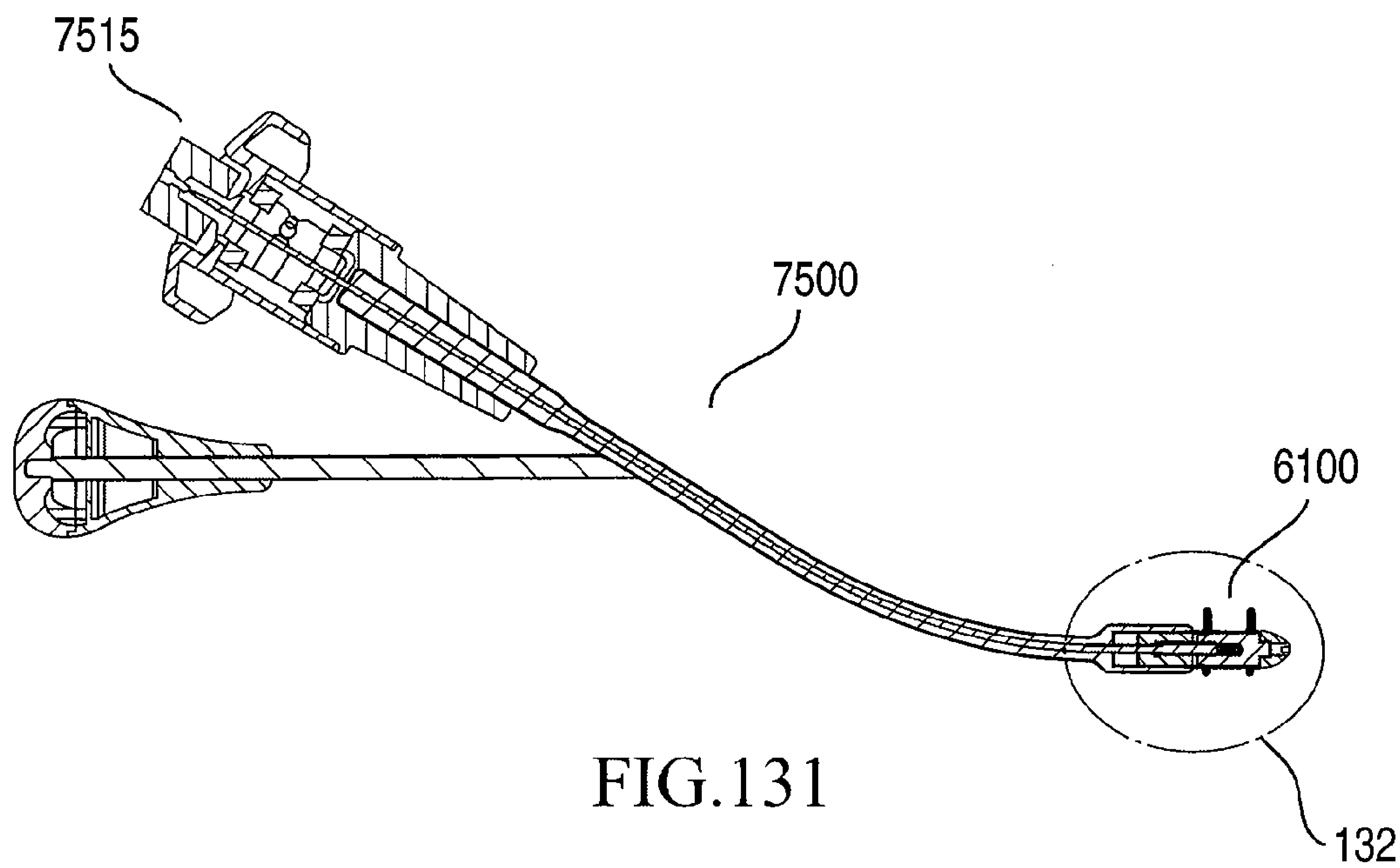


FIG.131

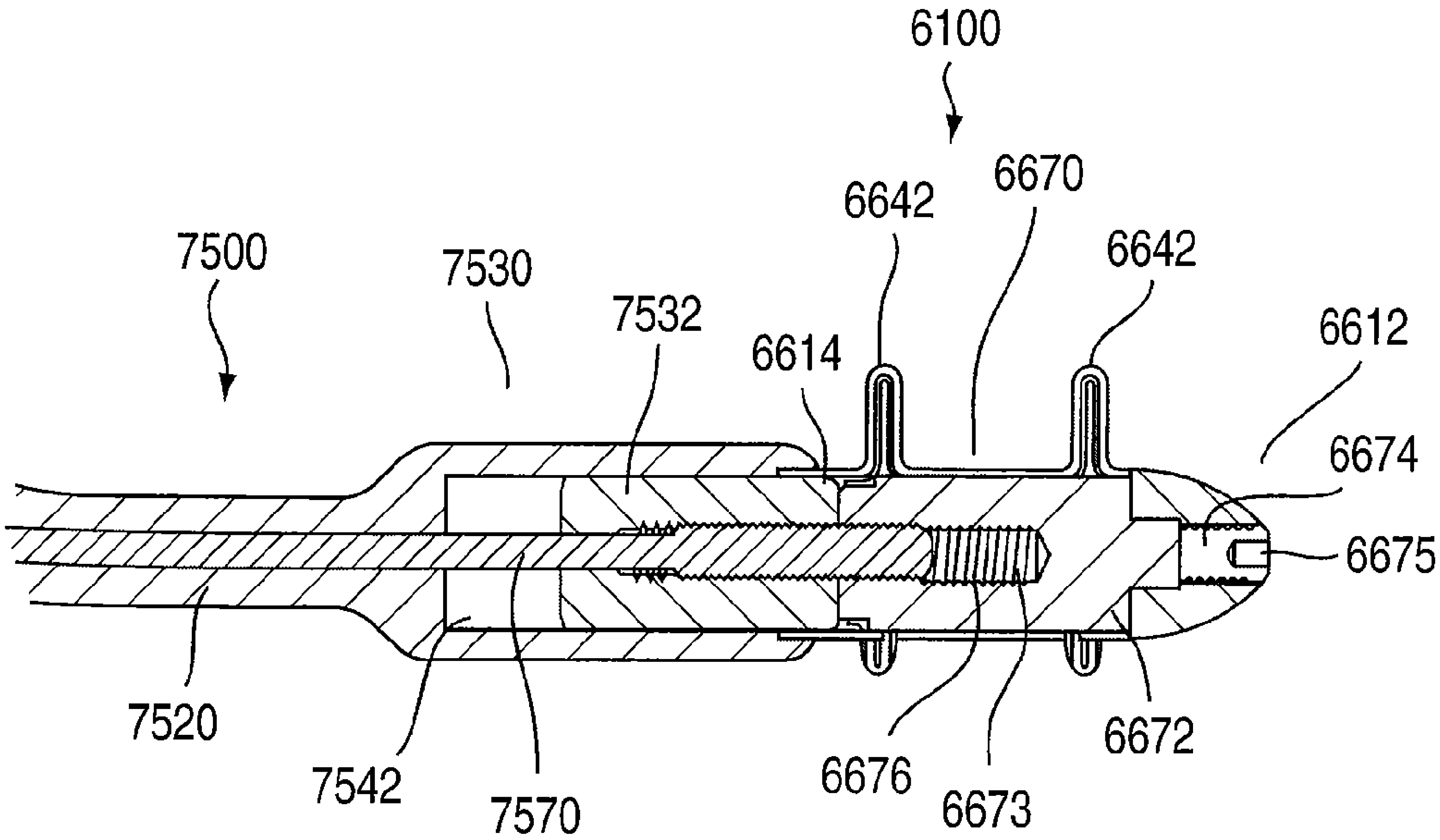


FIG.132

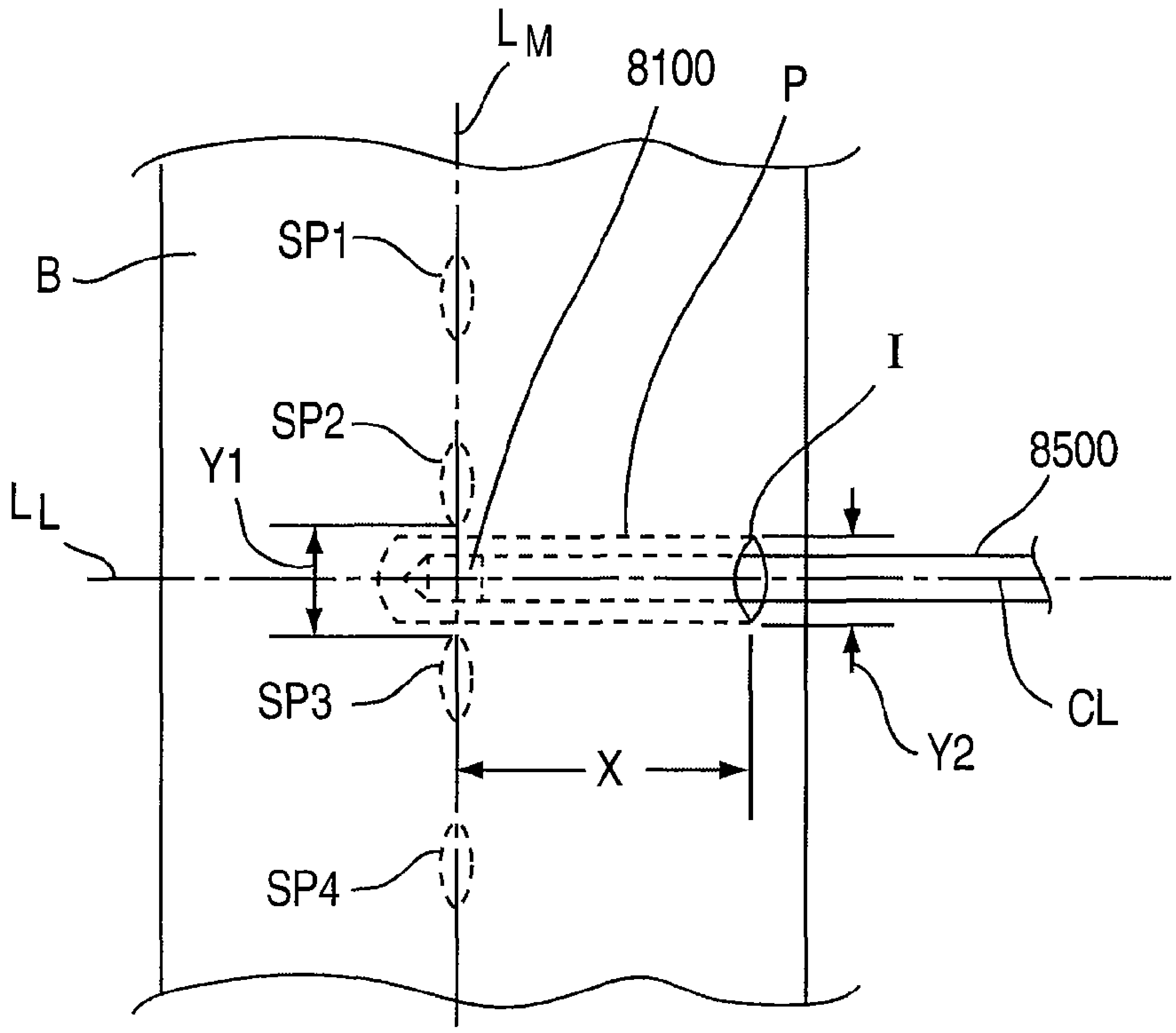


FIG.133

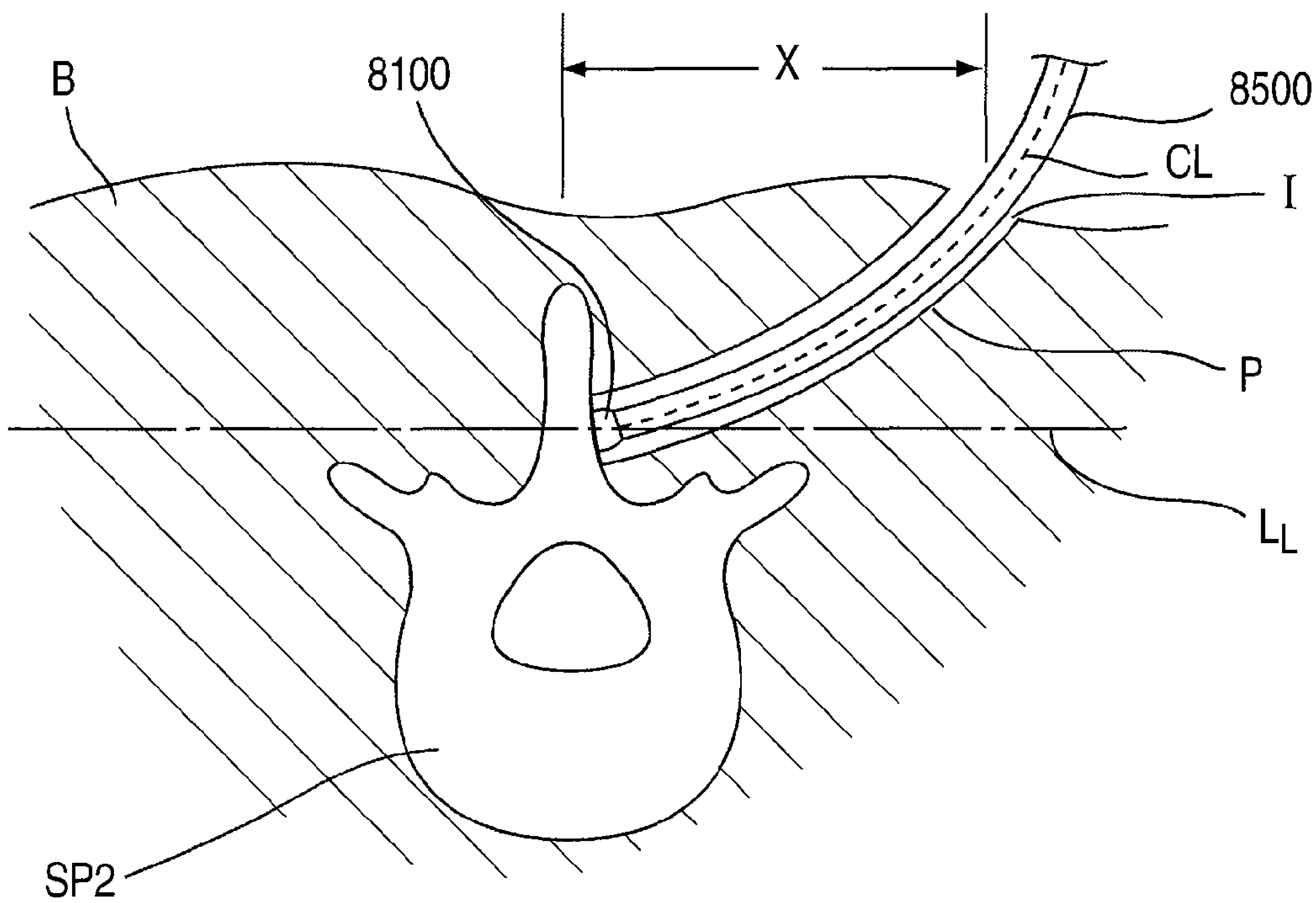


FIG.134

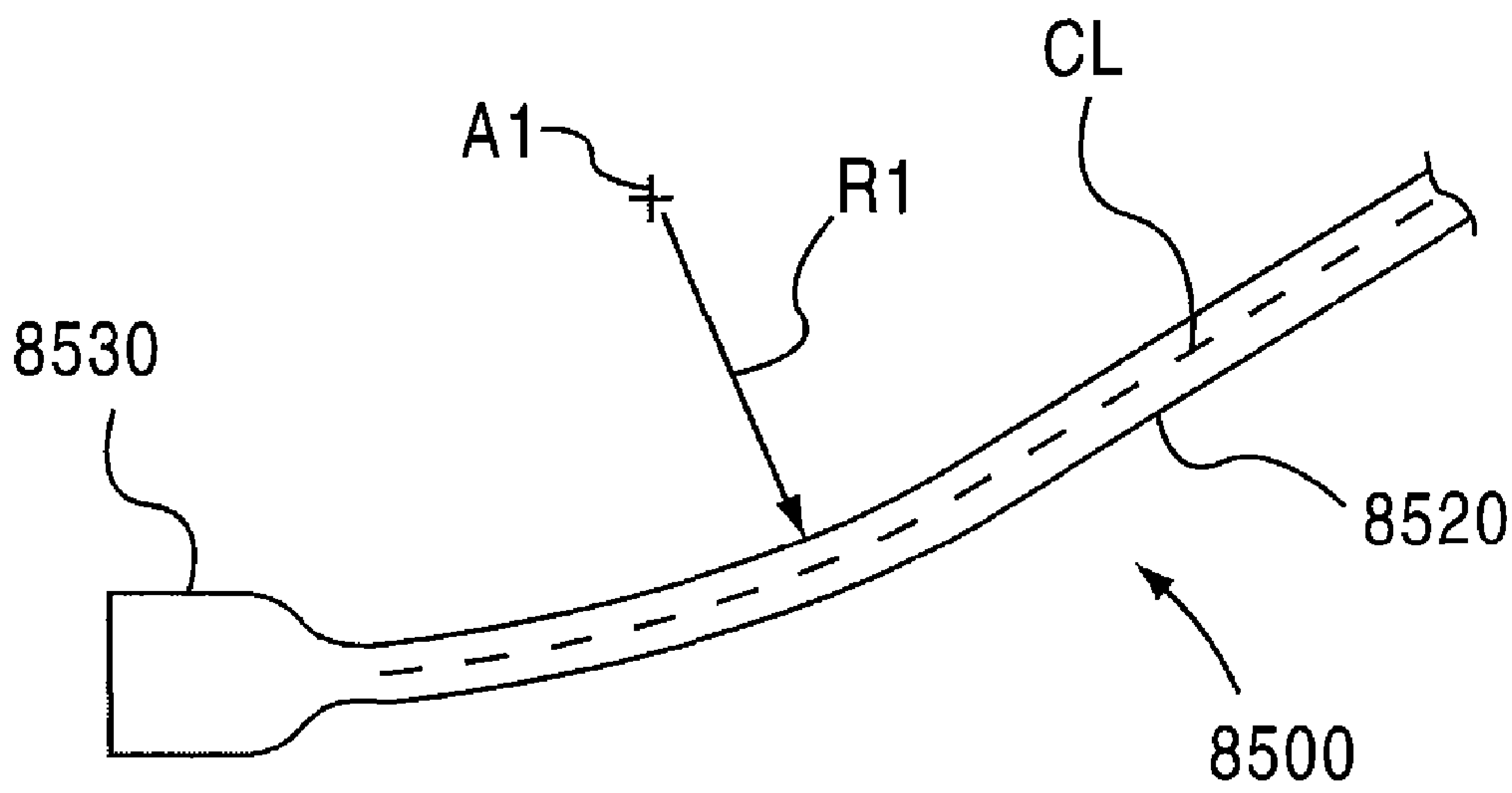


FIG.135

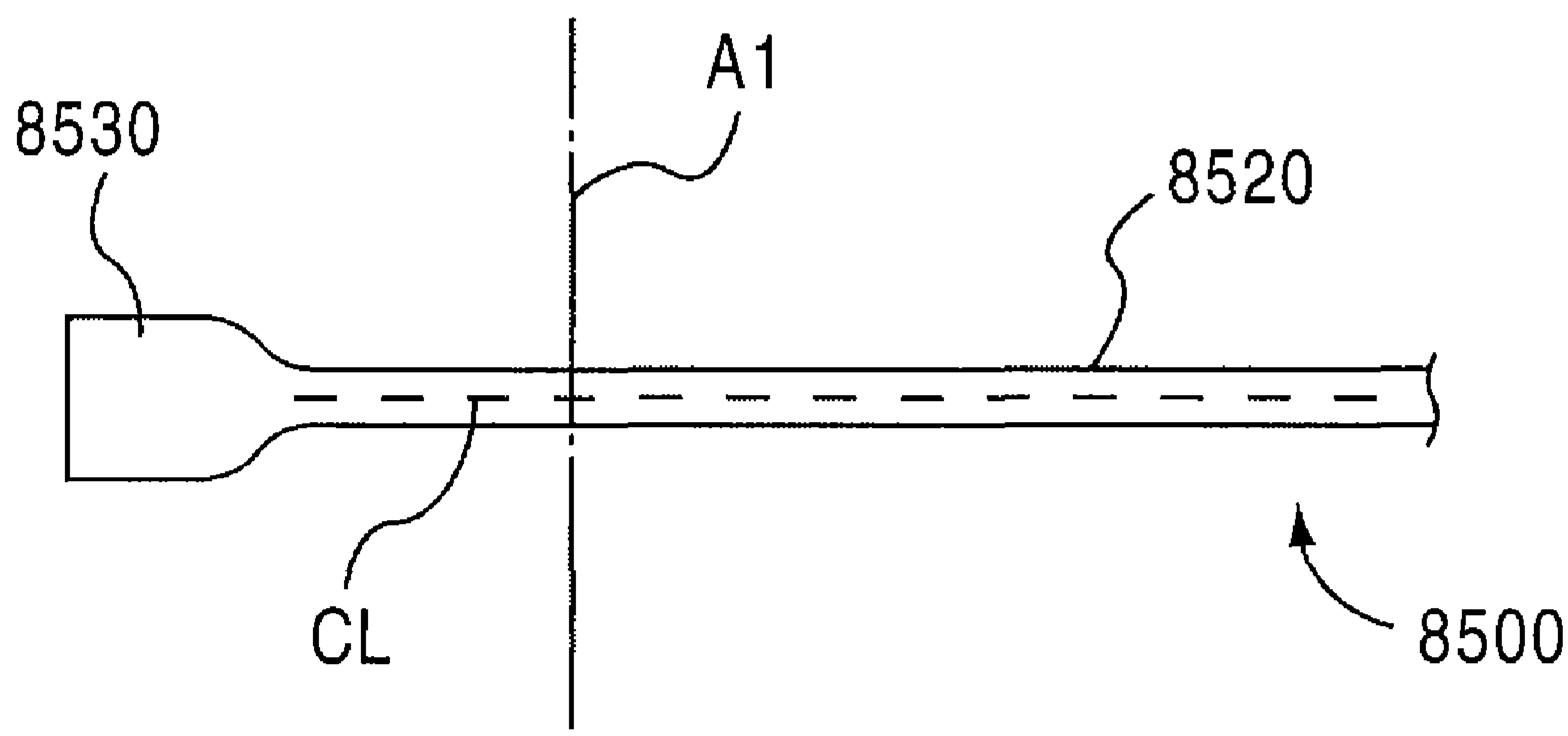


FIG.136

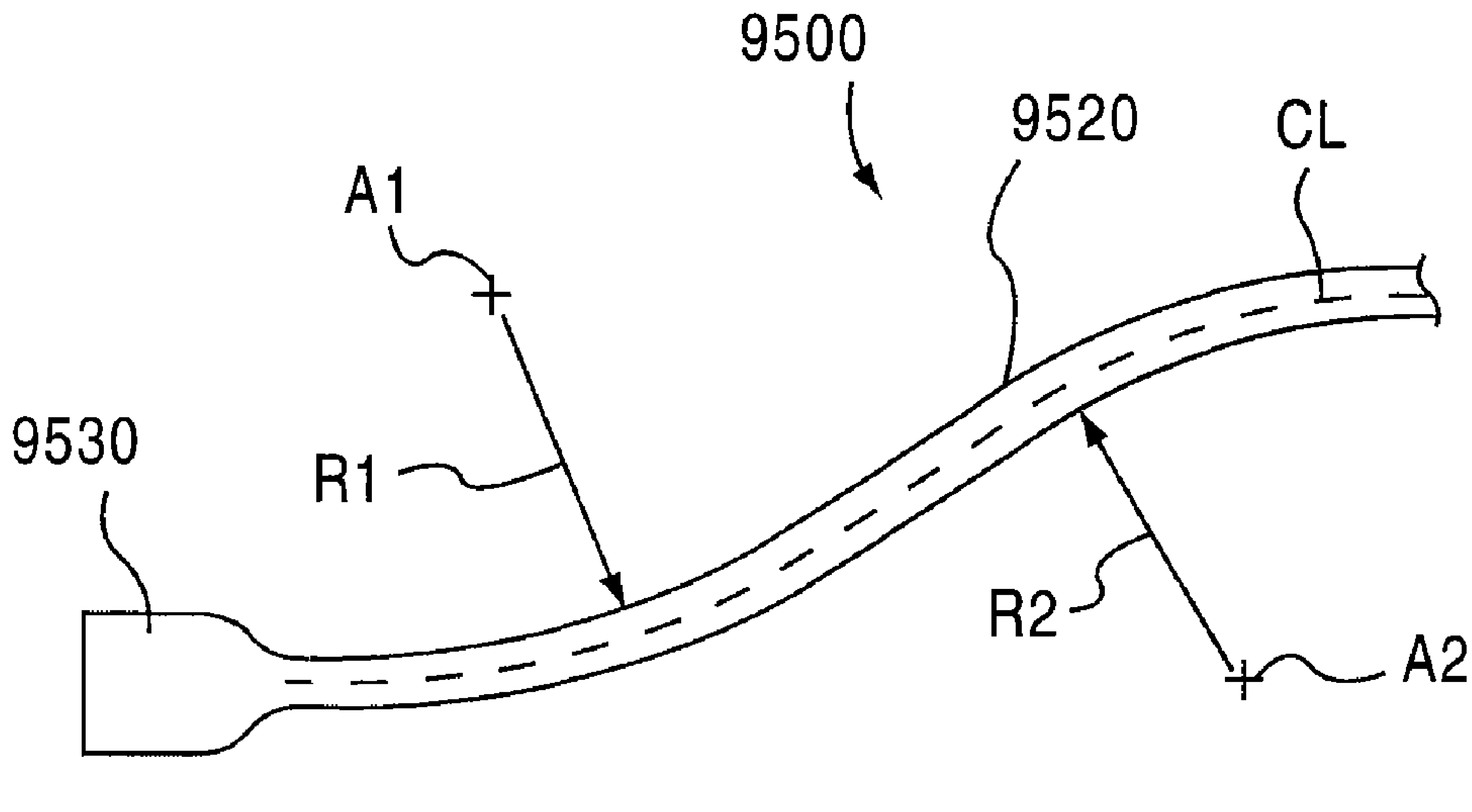


FIG.137

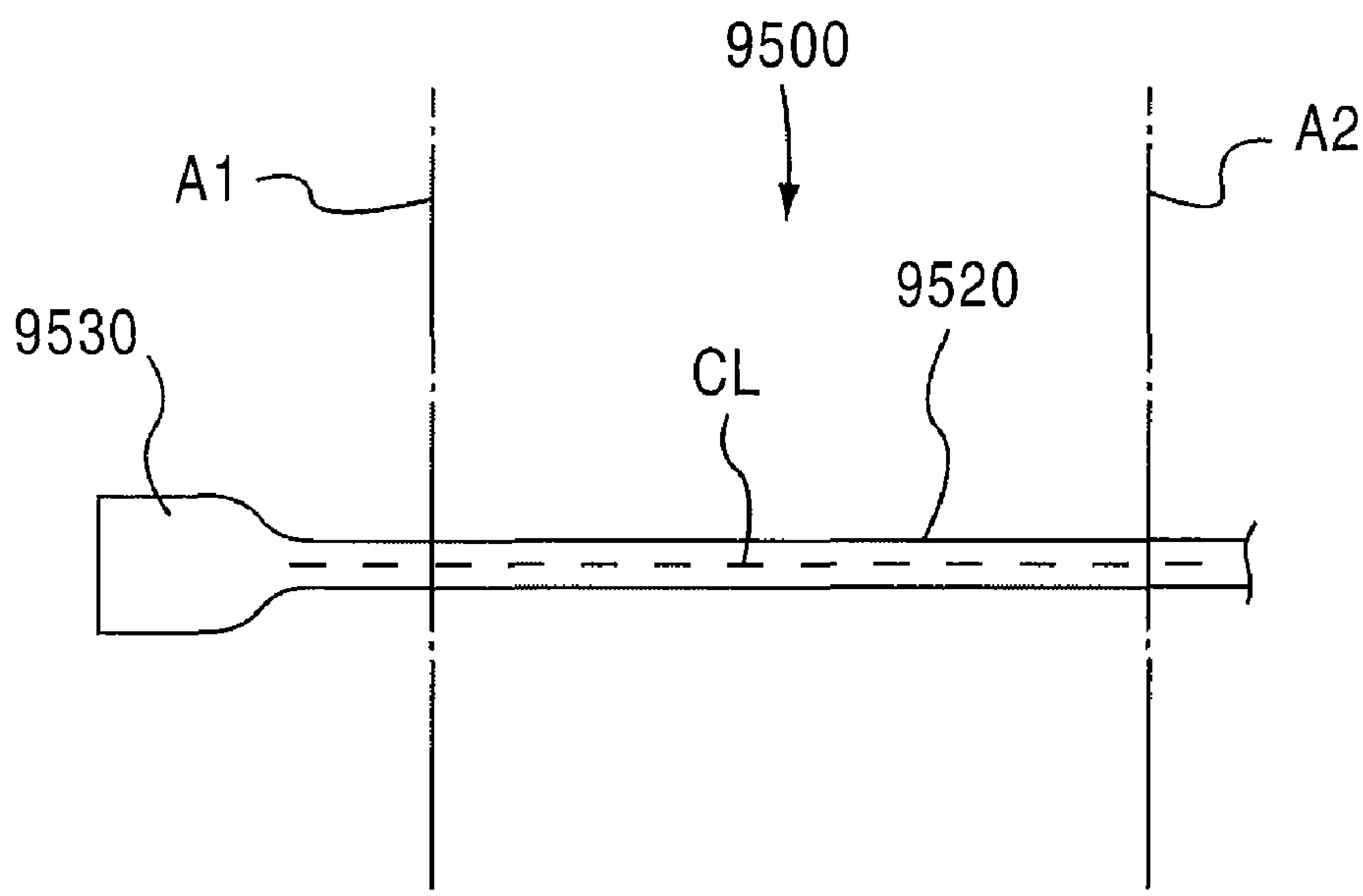
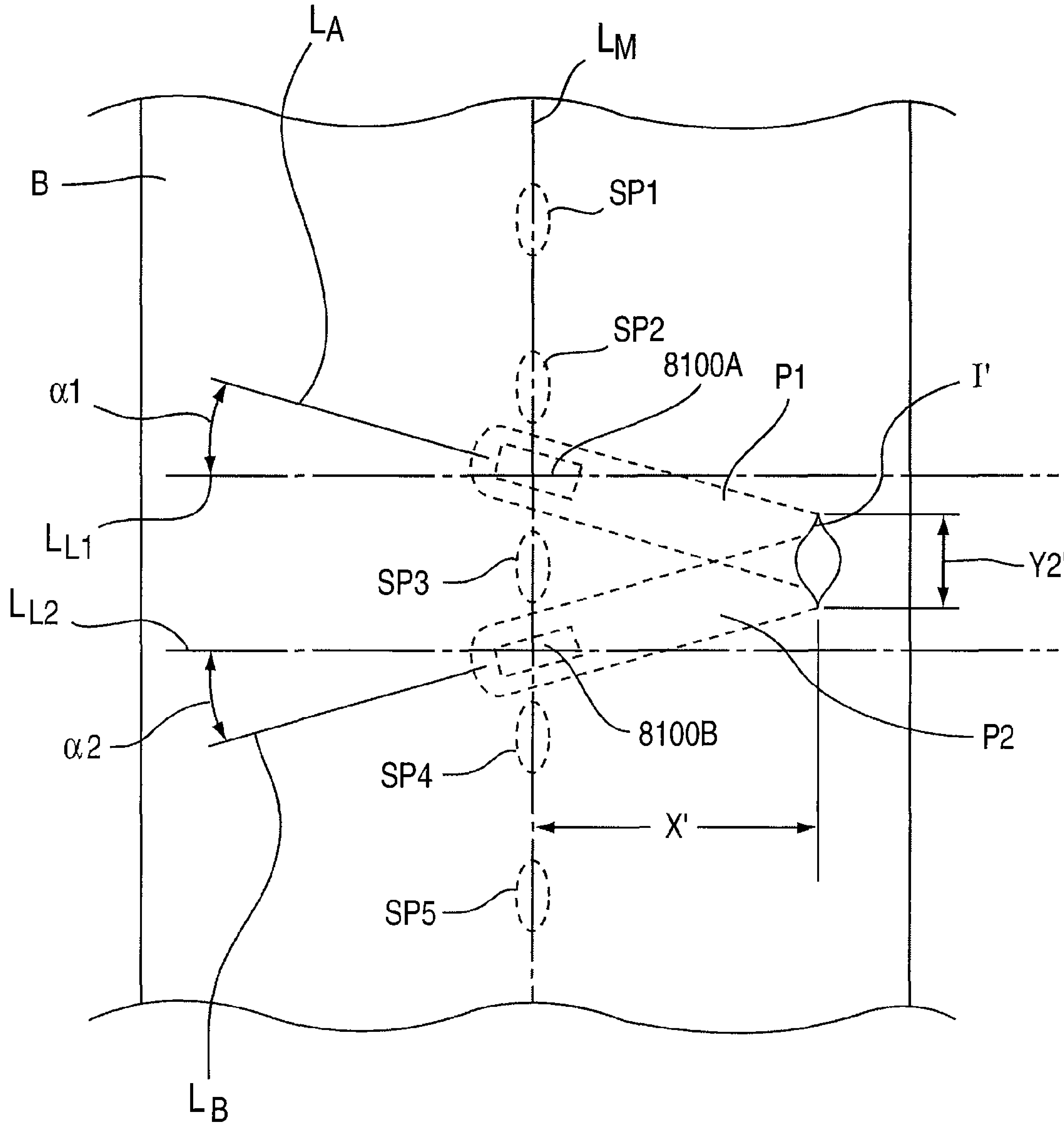


FIG.138



L_A
L_M
B
SP1
SP2
8100A
P1
I'
α1
L_{L1}
SP3
Y2'
L_{L2}
α2
8100B
P2
SP4
X'
SP5
L_B

FIG.139

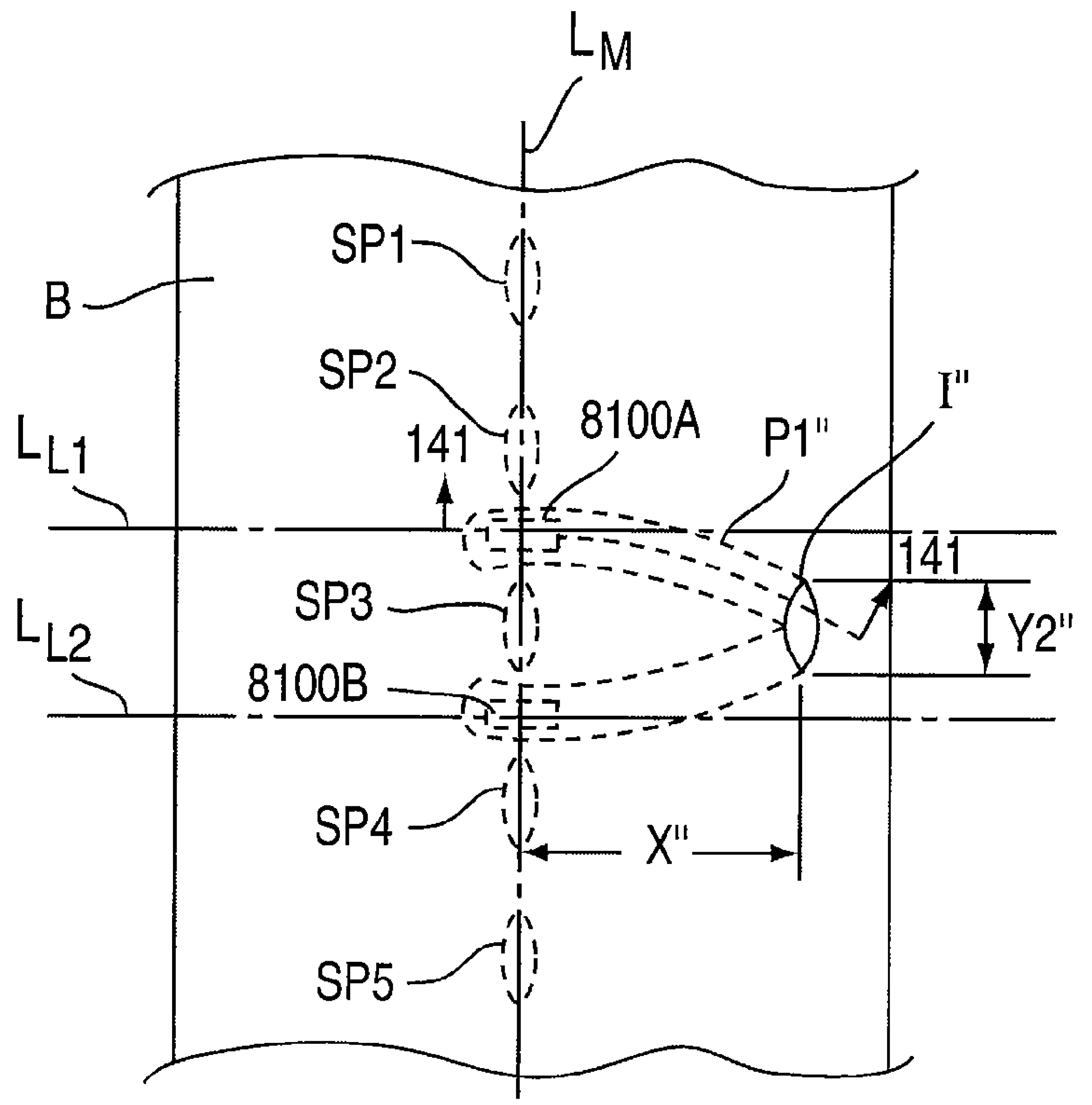


FIG.140

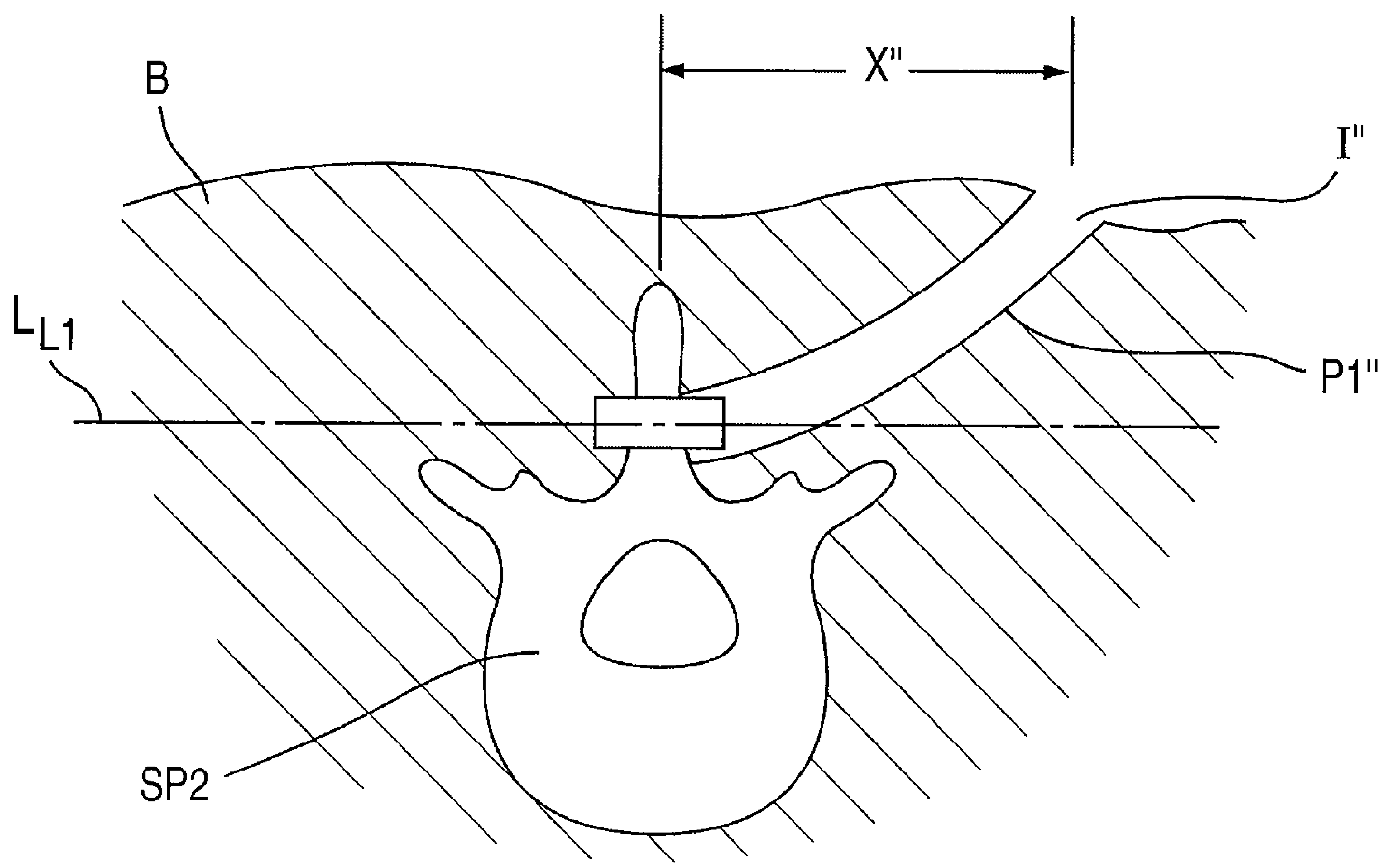


FIG.141

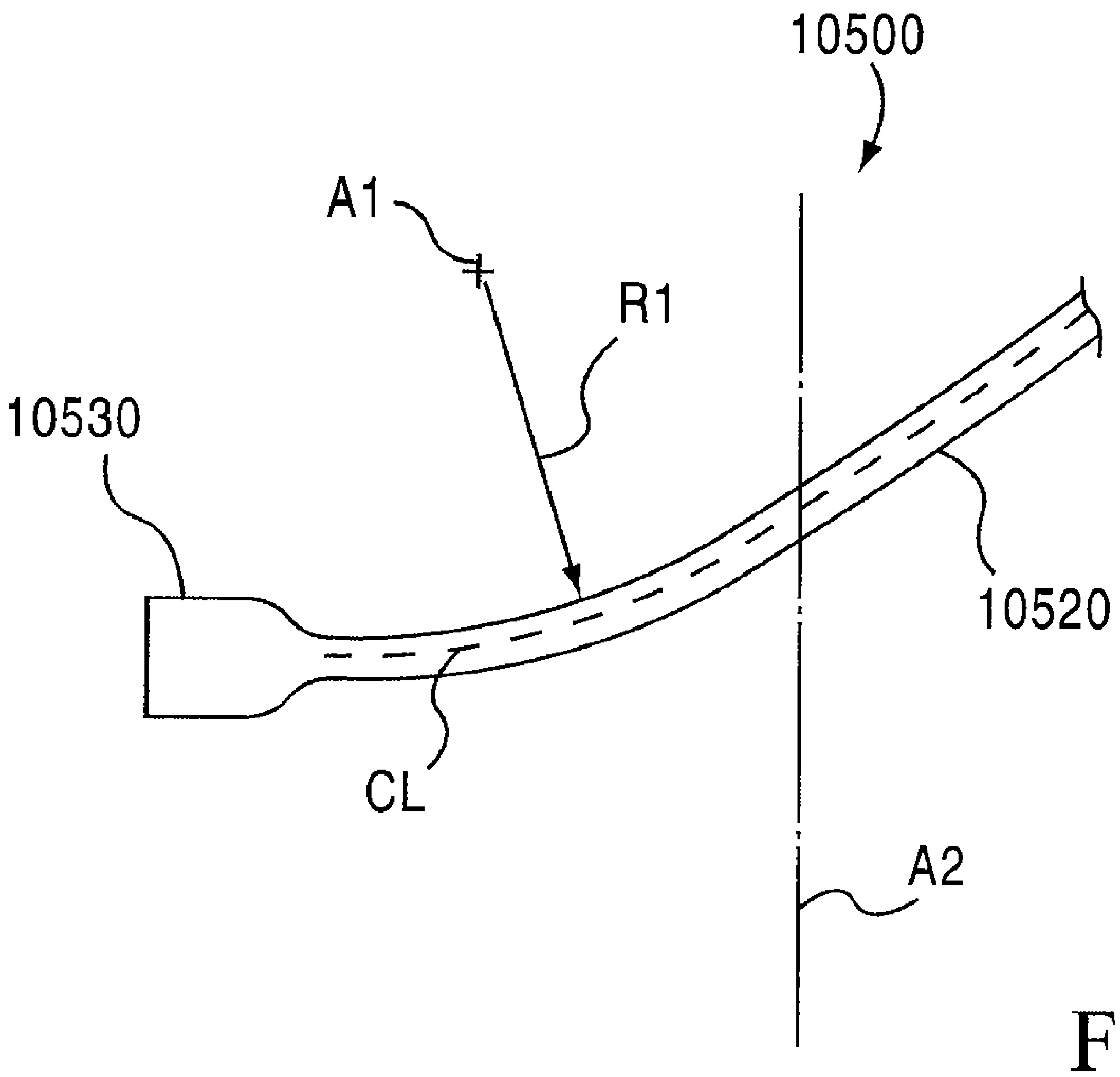


FIG. 142

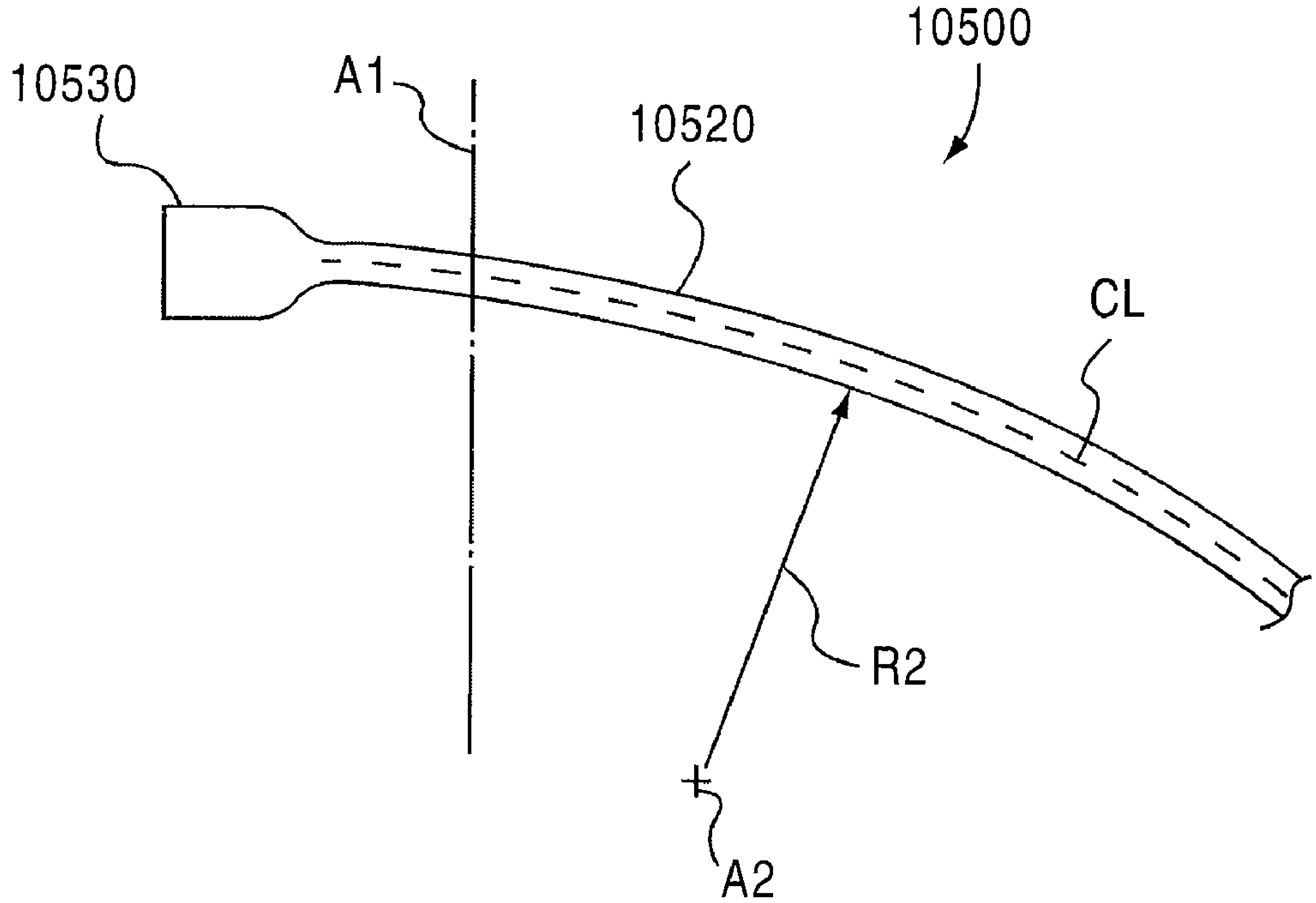


FIG. 143

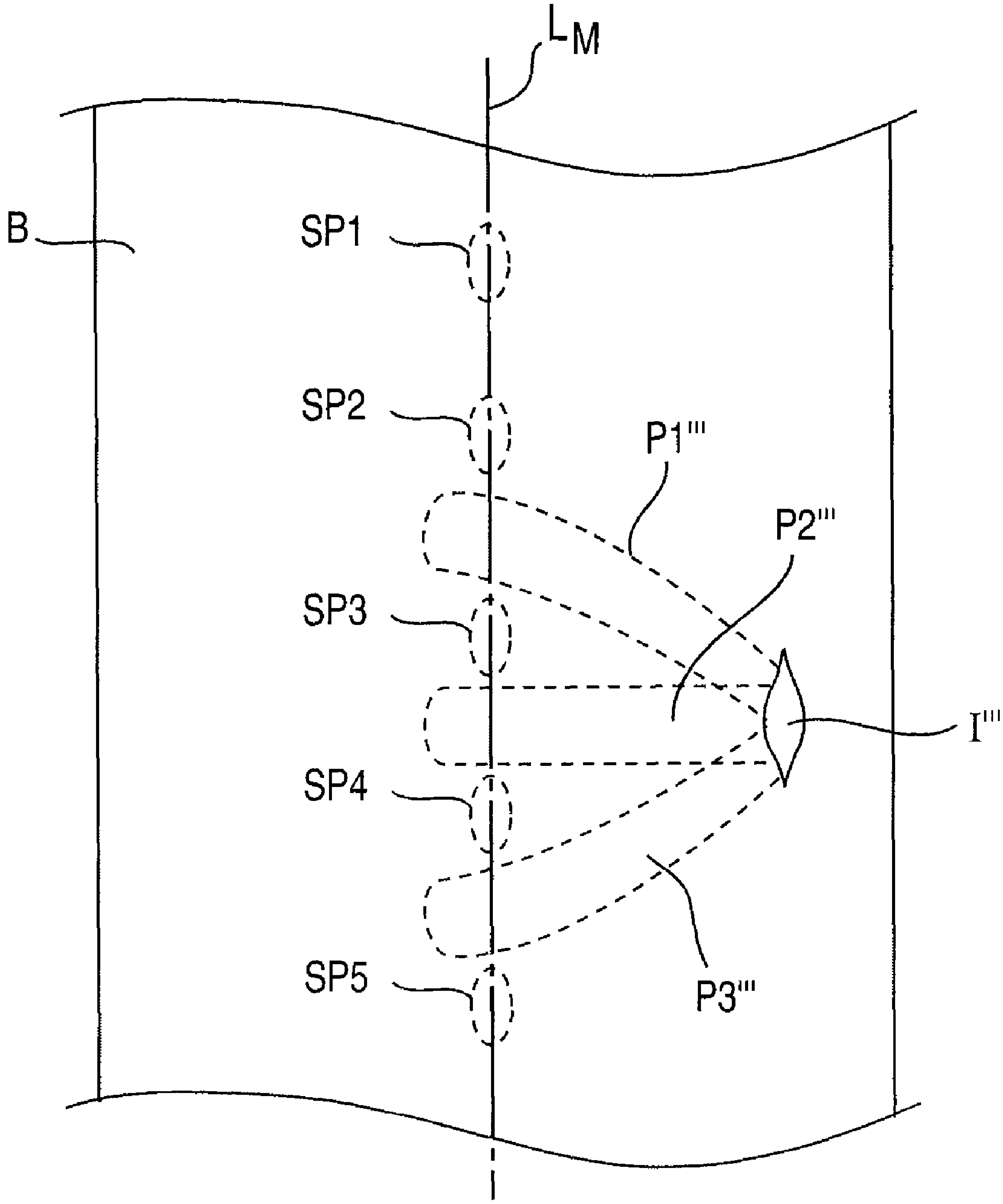


FIG.144

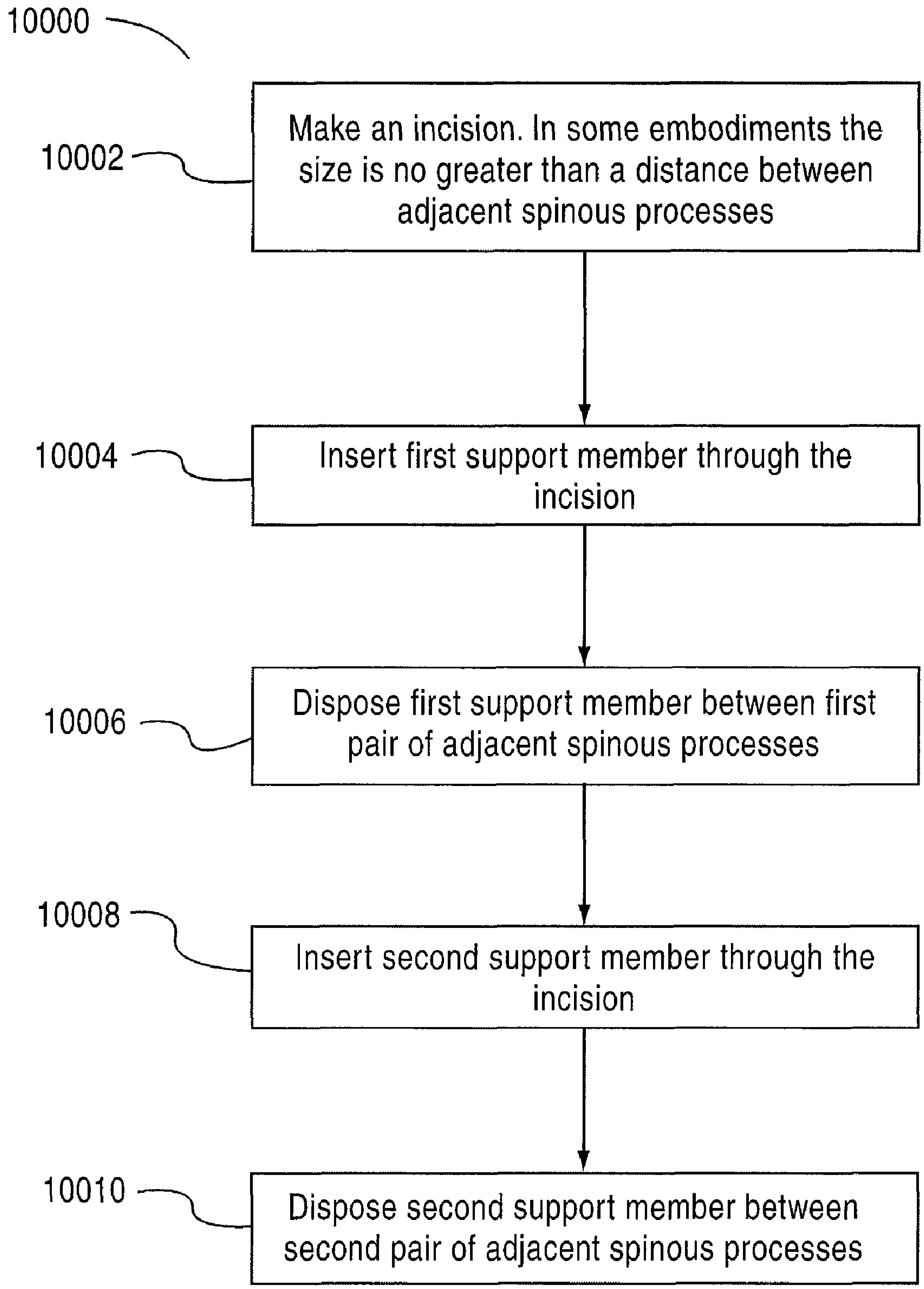

10000
10002
Make an incision. In some embodiments the size is no greater than a distance between adjacent spinous processes
10004
Insert first support member through the incision
10006
Dispose first support member between first pair of adjacent spinous processes
10008
Insert second support member through the incision
10010
Dispose second support member between second pair of adjacent spinous processes

FIG. 145

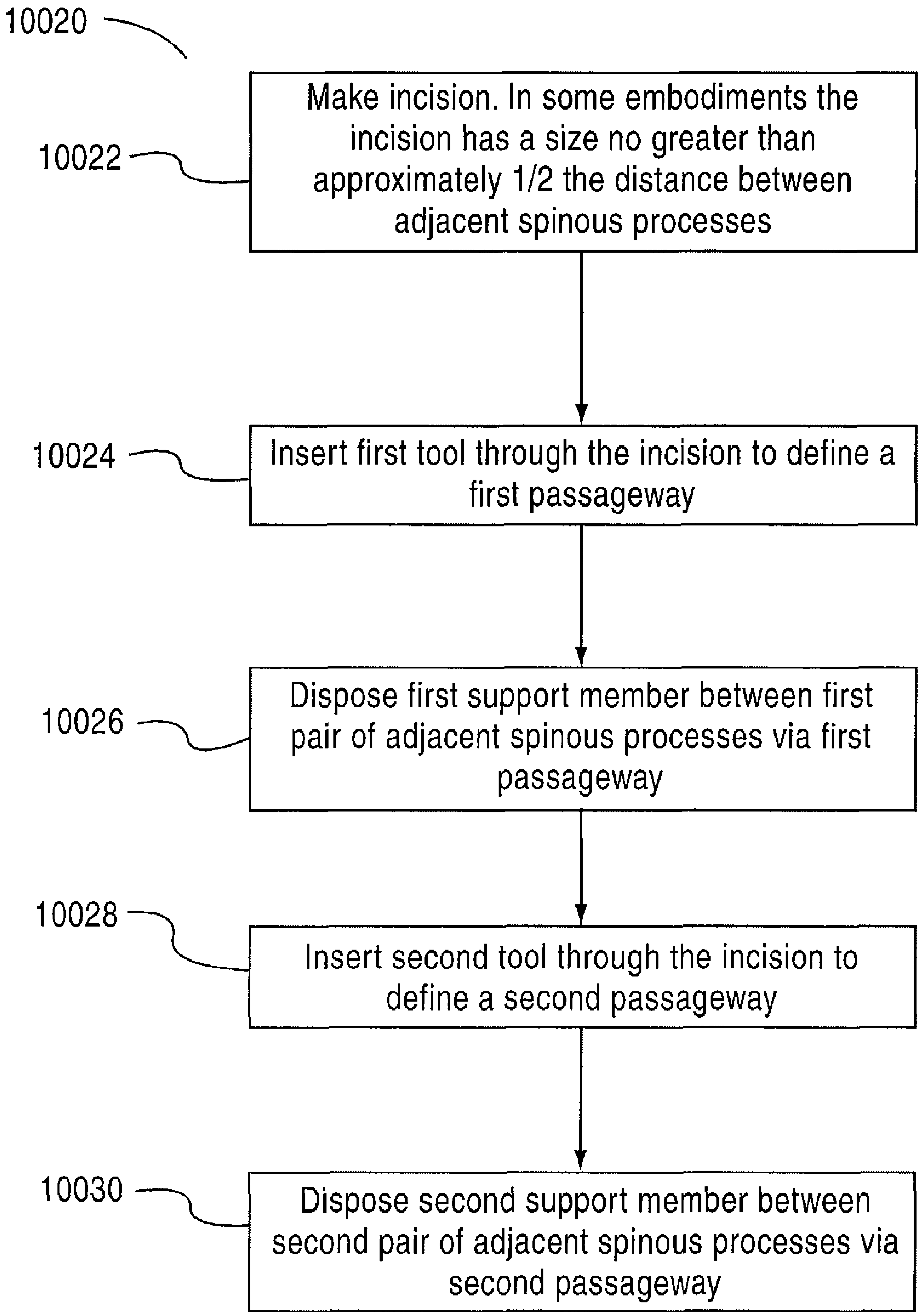

10020
10022
Make incision. In some embodiments the incision has a size no greater than approximately 1/2 the distance between adjacent spinous processes
10024
Insert first tool through the incision to define a first passageway
10026
Dispose first support member between first pair of adjacent spinous processes via first passageway
10028
Insert second tool through the incision to define a second passageway
10030
Dispose second support member between second pair of adjacent spinous processes via second passageway

FIG.146

PERCUTANEOUS SPINAL IMPLANTS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 11/625,604, entitled "Percutaneous Spinal Implants and Methods," filed Jan. 22, 2007, which is a continuation-in-part of each of U.S. patent application Ser. Nos. 11/454,153, 11/454,156 and 11/454,194, each entitled "Percutaneous Spinal Implants and Methods," and filed Jun. 16, 2006, each of which is a continuation-in-part of International Patent Application No. PCT/US2006/005580, entitled "Percutaneous Spinal Implants and Methods," filed Feb. 17, 2006. Each of U.S. patent application Ser. Nos. 11/454,153, 11/454,156 and 11/454,194 is also a continuation-in-part of U.S. patent application Ser. No. 11/059,526, entitled "Apparatus and Method for Treatment of Spinal Conditions," filed Feb. 17, 2005. Each of U.S. patent application Ser. Nos. 11/454,153, 11/454,156 and 11/454,194 is also a continuation-in-part of U.S. patent application Ser. No. 11/252,879, entitled "Percutaneous Spinal Implants and Methods," filed Oct. 19, 2005, which is a continuation-in-part of U.S. patent application Ser. No. 11/059,526, entitled "Apparatus and Method for Treatment of Spinal Conditions," filed Feb. 17, 2005, and which claims the benefit of U.S. Provisional Application Ser. No. 60/695,836 entitled "Percutaneous Spinal Implants and Methods," filed Jul. 1, 2005. Each of U.S. patent application Ser. Nos. 11/454,153, 11/454,156 and 11/454,194 is also a continuation-in-part of U.S. patent application Ser. No. 11/252,880, now abandoned entitled "Percutaneous Spinal Implants and Methods," filed Oct. 19, 2005, which is a continuation-in-part of U.S. patent application Ser. No. 11/059,526, entitled "Apparatus and Method for Treatment of Spinal Conditions," filed Feb. 17, 2005, and which claims the benefit of U.S. Provisional Application Ser. No. 60/695,836 entitled "Percutaneous Spinal Implants and Methods," filed Jul. 1, 2005. Each of the above-identified applications is incorporated herein by reference in its entirety.

U.S. patent application Ser. No. 11/625,604 is also a continuation-in-part of each of U.S. patent application Ser. Nos. 11/356,301, 11/356,302, 11/356,296, 11/356,295 and 11/356,294, each entitled "Percutaneous Spinal Implants and Methods," filed Feb. 17, 2006. Each of U.S. patent application Ser. Nos. 11/356,301, 11/356,302, 11/356,296, 11/356,295 and 11/356,294 is a continuation-in-part of U.S. patent application Ser. Nos. 11/252,879 and 11/252,880, each entitled "Percutaneous Spinal Implants and Methods," and filed Oct. 19, 2005, each of which is a continuation-in-part of U.S. patent application Ser. No. 11/059,526, entitled "Apparatus and Method for Treatment of Spinal Conditions," filed Feb. 17, 2005, and each of which claims the benefit of U.S. Provisional Application Ser. No. 60/695,836 entitled "Percutaneous Spinal Implants and Methods," filed Jul. 1, 2005. Each of the above-identified applications is incorporated herein by reference in its entirety.

U.S. patent application Ser. No. 11/625,604 is also a continuation-in-part of International Patent Application No. PCT/US2006/005580, entitled "Percutaneous Spinal Implants and Methods," filed Feb. 17, 2006; and is a continuation-in-part of U.S. patent application Ser. No. 11/059,526, entitled "Apparatus and Method for Treatment of Spinal Conditions," filed Feb. 17, 2005. Each of the above-identified applications is incorporated herein by reference in its entirety.

U.S. patent application Ser. No. 11/625,604 is also and is a continuation-in-part of each of U.S. patent application Ser. Nos. 11/252,879 and 11/252,880, each entitled "Percutaneous Spinal Implants and Methods," filed Oct. 19, 2005, each of which is a continuation-in-part of U.S. patent application Ser. No. 11/059,526, entitled "Apparatus and Method for Treatment of Spinal Conditions," filed Feb. 17, 2005, and each of which claims the benefit of U.S. Provisional Application Ser. No. 60/695,836 entitled "Percutaneous Spinal Implants and Methods," filed Jul. 1, 2005. Each of the above-identified applications is incorporated herein by reference in its entirety.

U.S. patent application Ser. No. 11/625,604 also claims the benefit of U.S. Provisional Application Ser. No. 60/869,038, entitled "Percutaneous Spinal Implants and Methods," filed on Dec. 7, 2006, which is incorporated herein by reference in its entirety.

This application is related to U.S. patent application Ser. Nos. 11/927,824, 11/927,830 and 11/927,835 each entitled "Percutaneous Spinal Implants and Methods," filed on even date herewith, and incorporated herein by reference in their entirety.

BACKGROUND

The invention relates generally to the treatment of spinal conditions, and more particularly, to the treatment of spinal compression using percutaneous spinal implants for implantation between adjacent spinous processes.

A back condition that impacts many individuals is spinal stenosis. Spinal stenosis is a progressive narrowing of the spinal canal that causes compression of the spinal cord. Each vertebra in the spinal column has an opening that extends through it. The openings are aligned vertically to form the spinal canal. The spinal cord runs through the spinal canal. As the spinal canal narrows, the spinal cord and nerve roots extending from the spinal cord and between adjacent vertebrae are compressed and may become inflamed. Spinal stenosis can cause pain, weakness, numbness, burning sensations, tingling, and in particularly severe cases, may cause loss of bladder or bowel function, or paralysis. The legs, calves and buttocks are most commonly affected by spinal stenosis, however, the shoulders and arms may also be affected.

Mild cases of spinal stenosis may be treated with rest or restricted activity, non-steroidal anti-inflammatory drugs (e.g., aspirin), corticosteroid injections (epidural steroids), and/or physical therapy. Some patients find that bending forward, sitting or lying down may help relieve the pain. This may be due to bending forward creates more vertebral space, which may temporarily relieve nerve compression. Because spinal stenosis is a progressive disease, the source of pressure may have to be surgically corrected (decompressive laminectomy) as the patient has increasing pain. The surgical procedure can remove bone and other tissues that have impinged upon the spinal canal or put pressure on the spinal cord. Two adjacent vertebrae may also be fused during the surgical procedure to prevent an area of instability, improper alignment or slippage, such as that caused by spondylolisthesis. Surgical decompression can relieve pressure on the spinal cord or spinal nerve by widening the spinal canal to create more space. This procedure requires that the patient be given a general anesthesia as an incision is made in the patient to access the spine to remove the areas that are contributing to the pressure. This procedure, however, may result in blood loss and an increased chance of significant complications, and usually results in an extended hospital stay.

Minimally-invasive procedures have been developed to provide access to the space between adjacent spinous processes such that major surgery is not required. Such known procedures, however, may not be suitable in conditions where the spinous processes are severely compressed. Moreover, such procedures typically involve large or multiple incisions.

Thus, a need exists for improvements in the treatment of spinal conditions such as spinal stenosis.

SUMMARY OF THE INVENTION

Medical devices and related methods for the treatment of spinal conditions are described herein. In some embodiments, a method includes placement of two or more support members (e.g., spacers, inter-spinous implants, expandable devices, extension limiting devices or the like) at two or more inter-spinous spaces through a single incision. Tools configured to facilitate placement of two or more support members at different locations along the length of the patient's spine through a single incision are also described herein. In one embodiment, the tools are configured with one or more curvatures such that support members that are introduced through the same incision can be directed towards different inter-spinous locations along the length of a patient's spine.

In some embodiments, a method includes positioning a medical device within a body between adjacent spinous processes, moving the medical device from a collapsed configuration to an expanded configuration within the body using an actuator removably coupled to the medical device, and removing the actuator from the body while the medical device remains between the adjacent spinous processes.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a first configuration adjacent two adjacent spinous processes.

FIG. **2** is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a second configuration adjacent two adjacent spinous processes.

FIG. **3** is a schematic illustration of a deforming element according to an embodiment of the invention in a first configuration.

FIG. **4** is a schematic illustration of a side view of the expanding element illustrated in FIG. **3**.

FIG. **5** is a side view of a medical device according to an embodiment of the invention in a first configuration.

FIG. **6** is a side view of the medical device illustrated in FIG. **5** in a second configuration.

FIG. **7** is a perspective view of a medical device according to an embodiment of the invention in a first configuration.

FIG. **8** is a posterior view of a medical device according to an embodiment of the invention, a portion of which is in a second configuration.

FIG. **9** is a posterior view of the medical device illustrated in FIG. **7** fully deployed in the second configuration.

FIG. **10** is a front plan view of the medical device illustrated in FIG. **7** in the second configuration.

FIG. **11** is a cross-sectional, side view of a medical device according to another embodiment of the invention in a first configuration.

FIG. **12** is a cross sectional, side view of the medical device illustrated in FIG. **11** in a partially expanded configuration.

FIG. **13** is a posterior view of the medical device illustrated in FIG. **11** inserted between adjacent spinous processes in a second configuration.

FIG. **14** is a lateral view of the medical device illustrated in FIG. **11** inserted between adjacent spinous processes in a second configuration.

FIG. **15** is a perspective view of an implant expansion device according to an embodiment of the invention.

FIG. **15**A is a cross-sectional view of a portion of the device illustrated in FIG. **15**, taken along line A-A in FIG. **15**.

FIG. **15**B is a cross-sectional view of a portion of the device illustrated in FIG. **15** in a first configuration, taken along line B-B in FIG. **15**.

FIG. **15**C is a cross-sectional view of a portion of the device illustrated in FIG. **15** in a second configuration, taken along line C-C in FIG. **15**.

FIG. **16** is an alternative perspective view of the implant expansion device illustrated in FIG. **15**.

FIG. **17** is a perspective view of a portion of the implant expansion device illustrated in FIG. **15**.

FIG. **18** is a perspective view of an implant expansion device according to an embodiment of the invention in a first position.

FIG. **19** is a perspective view of the implant expansion device illustrated in FIG. **18** in a second position.

FIG. **20** is a partial cross-sectional illustration of the implant expansion device as illustrated in FIG. **18** inserted in a spinal implant.

FIG. **21** is a partial cross-sectional illustration of the implant expansion device as illustrated in FIG. **19** inserted in a spinal implant.

FIG. **22** is a side view of a partially expanded spinal implant.

FIG. **23** is a side view of an expanded spinal implant.

FIG. **24** is a cross-sectional, side view of an implant expansion device according to an alternative embodiment of the invention in a first configuration.

FIG. **25** is a cross-sectional, side view of the implant expansion device illustrated in FIG. **24** in a second configuration.

FIG. **26** is a cross-sectional, plan view of an implant expansion device according to a further embodiment of the invention in a first configuration.

FIG. **27** is a partial side view of an implant for use with the implant expansion device illustrated in FIG. **26**.

FIG. **28** is a cross-sectional, plan view of the implant expansion device illustrated in FIG. **26** in a second configuration.

FIG. **29** is a cross-sectional, plan view of an implant expansion device according to another embodiment of the invention in a first configuration.

FIG. **30** is a cross-sectional, side view of the implant expansion device illustrated in FIG. **29**.

FIGS. **31** and **32** illustrate a posterior view of a spinal implant expandable by an expansion device implant expander according to another embodiment of the invention in a first configuration and a second configuration, respectively.

FIG. **33** illustrates a cross-sectional, side view of a spinal implant according to an embodiment of the invention.

FIG. **34** is a cross-sectional, side view and FIG. **35** is a side view of an implant expansion device according to an embodiment of the invention for use with the spinal implant illustrated in FIG. **33**.

FIGS. **36** and **37** illustrate the use of the implant expansion device illustrated in FIGS. **34** and **35** with the spinal implant illustrated in FIG. **33**.

FIG. **38** is a schematic illustration of an apparatus according to an embodiment of the invention.

FIG. **39** is a front plan view of an apparatus according to an embodiment of the invention and a portion of a spine.

FIG. **40** is a cross-sectional view of a component of the apparatus and the portion of the spine illustrated in FIG. **39**, taken along line **40-40** in FIG. **39**.

FIG. **41** is a side plan view of the apparatus illustrated in FIG. **39**.

FIG. **42** is a side plan view of a component of the apparatus illustrated in FIG. **39**.

FIG. **43** is a front plan view of the component of the apparatus illustrated in FIG. **42**.

FIG. **44** is a partial cross-sectional view of a detachable trocar tip for use with an apparatus according to an embodiment of the invention in a first configuration.

FIG. **45** is a partial cross-sectional view of the detachable trocar tip for use with the apparatus according to an embodiment of the invention in a second configuration.

FIG. **46** is a partial exploded view of a detachable trocar tip for use with the apparatus according to an embodiment of the invention.

FIG. **47** is a side plan view of a medical device according to another embodiment of the invention.

FIG. **48** is a perspective view of a medical device according to another embodiment of the invention.

FIG. **49***a* is a perspective view of an apparatus according to an embodiment of the invention.

FIG. **49***b* is an exploded view of a portion of the apparatus illustrated in FIG. **49***a*.

FIG. **49***c* is an exploded view of a portion of the apparatus illustrated in FIG. **49***a*.

FIG. **50** is a perspective view of a spacer configured to be inserted between adjacent spinous processes according to an embodiment of the invention.

FIG. **51** is a side view of a spacer according to an embodiment of the invention in a first configuration inserted between adjacent spinous processes.

FIG. **52** is a side view of the spacer illustrated in FIG. **49** in a second configuration inserted between adjacent spinous processes.

FIGS. **53-55** are illustrations of spacers according to alternative embodiments of the invention.

FIG. **56** is a side view of a spacer according to an alternative embodiment of the invention in a first configuration.

FIG. **57** is a side view of the spacer illustrated in FIG. **56** in a second configuration inserted between adjacent spinous processes.

FIG. **58** is a side view of a spacer according to a further alternative embodiment of the invention inserted between adjacent spinous processes.

FIG. **59** is a side view of a spacer according to another alternative embodiment of the invention inserted between adjacent spinous processes.

FIGS. **60**A-**60**D are schematic illustrations of a posterior view of a medical device according to an embodiment of the invention in a first configuration (FIG. **60**A), a second (FIGS. **60**B and **60**D) configuration and a third configuration (FIG. **60**C).

FIGS. **61**A-**61**C are schematic illustrations of a posterior view of a medical device according to an embodiment of the invention in a first configuration, a second configuration and a third configuration, respectively.

FIGS. **62**A-**62**F are posterior views of a medical device according to an embodiment of the invention inserted between adjacent spinous processes in a first lateral positions and a second lateral position.

FIG. **63** is a lateral view of the medical device illustrated in FIGS. **62**A-**62**F inserted between adjacent spinous processes in a second configuration.

FIG. **64** is a lateral view of a medical device according to an embodiment of the invention inserted between adjacent spinous processes in a second configuration.

FIGS. **65**A and **65**B are front views of a medical device according to an embodiment of the invention in a first configuration and a second configuration, respectively.

FIG. **66**A is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a first configuration disposed between two adjacent spinous processes.

FIG. **66**B is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a second configuration disposed between two adjacent spinous processes.

FIGS. **67**A and **67**B are perspective views of a medical device according to an embodiment of the invention in a first configuration and a second configuration, respectively.

FIG. **68** is a posterior view of the medical device illustrated in FIGS. **67**A and **67**B disposed between adjacent spinous processes in a second configuration.

FIG. **69** is a lateral view taken from a proximal perspective A-A of the medical device illustrated in FIG. **68** disposed between adjacent spinous processes in a second configuration.

FIG. **70** is a cross-sectional front view of the medical device illustrated in FIGS. **67**A and **67**B in a second configuration.

FIG. **71** is a cross-sectional plan view taken along section A-A of the medical device illustrated in FIGS. **67**A and **67**B in a second configuration.

FIG. **72** is a cross-sectional front view of a medical device according to an embodiment of the invention in a second configuration.

FIGS. **73**A and **73**B are cross-sectional plan views taken along section A-A of the medical device illustrated in FIG. **72** in a second configuration and a first configuration, respectively.

FIG. **74** is a cross-sectional front view of a medical device according to an embodiment of the invention in a second configuration.

FIGS. **75**A through **75**C are cross-sectional plan views taken along section A-A of the medical device illustrated in FIG. **74** in a second configuration, a first configuration, and a third configuration respectively.

FIGS. **76**A and **76**B are cross-sectional front views of a medical device according to an embodiment of the invention in a second configuration and a first configuration, respectively.

FIG. **77** is a cross-sectional front view of a medical device according to an embodiment of the invention in a second configuration.

FIG. **78** is a cross-sectional plan view taken along section A-A of the medical device illustrated in FIG. **77** in a second configuration.

FIGS. **79**A and **79**B are perspective views of a medical device according to an embodiment of the invention in a second configuration and a first configuration, respectively.

FIGS. **80**A and **80**B are lateral views of a medical device according to an embodiment of the invention in a first configuration and a second configuration, respectively.

FIGS. **81**A and **81**B are perspective views of the medical device illustrated in FIGS. **80**A and **80**B in a first configuration and a second configuration, respectively.

FIG. **82** is a cross-sectional plan view of the medical device illustrated in FIGS. **80**A and **80**B in a second configuration.

FIG. **83** is a schematic illustration of a medical device according to an embodiment of the invention in a collapsed configuration adjacent two spinous processes.

FIG. **84** is a schematic illustration of the medical device of FIG. **83** in an expanded configuration adjacent two spinous processes.

FIG. **85** is a side perspective view of an implant according to an embodiment of the invention in an expanded configuration.

FIG. **86** is a side perspective view of the implant of FIG. **85** shown in a collapsed configuration.

FIG. **87** is a side perspective view of the medical device of FIG. **85** shown in a collapsed configuration.

FIG. **88** is a side view of a deployment tool according to an embodiment of the invention.

FIG. **89** is a side view of a portion of the deployment tool of FIG. **88** shown in a first configuration.

FIG. **90** is a side view of the portion of the deployment tool of FIG. **89** shown in a second configuration.

FIG. **91** is a side view of a portion of the deployment tool of FIG. **89** and the implant of FIG. **85** with the implant shown in an expanded configuration.

FIG. **92** is a cross-sectional view of the portion of the deployment tool and implant shown in FIG. **91**.

FIG. **93** is a cross-sectional view of the deployment tool and implant of FIG. **91** with the implant shown in a collapsed configuration positioned between adjacent spinous processes.

FIG. **94** is a side view of a portion of a medical device according to an embodiment of the invention illustrating an engaging portion in an extended configuration and positioned adjacent a spinous process.

FIG. **95** is a side view of the portion of the medical device of FIG. **94** illustrating the engaging portion in a partially collapsed configuration.

FIG. **96** is a side view of the portion of the medical device of FIG. **94** illustrating the engaging portion in the extended configuration after being inserted past the spinous process.

FIG. **97** is a side perspective view of the implant of FIG. **85** shown rotated about a longitudinal axis of the implant.

FIG. **98** is a side perspective view of an implant according to another embodiment of the invention.

FIG. **99** is a side view of a deployment tool according to another embodiment of the invention.

FIG. **100** is a side view of a deployment tool according to another embodiment of the invention.

FIG. **101** is a side view of a deployment tool according to another embodiment of the invention.

FIG. **102** is a side view of a deployment tool according to another embodiment of the invention.

FIG. **103** is a flow chart of a method according to an embodiment of the invention.

FIG. **104** is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a first configuration adjacent two adjacent spinous processes.

FIG. **105** is a schematic illustration of a posterior view of a medical device according to an embodiment of the invention in a second configuration adjacent two adjacent spinous processes.

FIG. **106** is a schematic illustration of a deforming element according to an embodiment of the invention in a first configuration.

FIG. **107** is a schematic illustration of a side view of the expanding element illustrated in FIG. **106**.

FIG. **108** is a side cross-sectional view of a medical device according to an embodiment of the invention in a first configuration.

FIG. **109** is a side cross-sectional view of the medical device illustrated in FIG. **108** in a second configuration.

FIG. **110** is a cross-sectional side view of a medical device and an actuator according to an embodiment of the invention with a portion of the medical device deployed in a second configuration.

FIG. **111** is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with the medical device fully deployed in the second configuration.

FIG. **112** is a side cross-sectional view of a medical device according to another embodiment of the invention in a first configuration.

FIG. **113** is a side cross-sectional view of the medical device illustrated in FIG. **112** in a second configuration.

FIG. **114** is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with a portion of the medical device moved back to its first configuration.

FIG. **115** is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with the medical device moved back to its first configuration.

FIG. **116** is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with a portion of the medical device moved back to its first configuration.

FIG. **117** is a side cross-sectional view of a medical device and an actuator according to an embodiment of the invention with the medical device moved back to its first configuration.

FIG. **118** is a side perspective view of an implant according to an embodiment of the invention shown in a collapsed configuration.

FIG. **119** is a cross-sectional view of the implant of FIG. **118** taken along line **119-119**.

FIG. **120** is a side perspective view of the implant of FIG. **118** shown in an expanded configuration.

FIG. **121** is a rear perspective view of the implant of FIG. **118** shown in a collapsed configuration.

FIG. **122** is cross-sectional view of the implant of FIG. **118** shown in a collapsed configuration taken along line **122-122**.

FIG. **123** is a rear perspective view of an implant according to an embodiment of the invention shown in a collapsed configuration.

FIG. **124** is a cross-sectional view of the implant of FIG. **123** shown in a collapsed configuration.

FIG. **125** is a perspective view of the implant of FIG. **123** in a collapsed configuration disposed on an expansion tool according to an embodiment of the invention.

FIG. **126** is a perspective view of the implant and the expansion tool of FIG. **125** taken along region **126**.

FIG. **127** is a side cross-sectional view of the implant and the expansion tool of FIG. **125**.

FIG. **128** is a side cross-sectional view of the implant and the expansion tool as shown in FIG. **127** taken along region **128**.

FIG. **129** is a perspective view of the implant of FIG. **123** in an expanded configuration disposed on an expansion tool according to an embodiment of the invention.

FIG. **130** is a perspective view of the implant and the expansion tool of FIG. **129** taken along region **130**.

FIG. **131** is a side cross-sectional view of the implant and the expansion tool of FIG. **129**.

FIG. **132** is a side cross-sectional view of the implant and the expansion tool as shown in FIG. **131** taken along region **132**.

FIG. **133** is a posterior view of a portion of a medical device according to an embodiment of the invention disposed within a body between a pair of spinous processes.

FIG. **134** is a side view of the portion of medical device shown in FIG. **133** taken along the lateral axis L_L.

FIGS. **135** and **136** are a side view and a top plan view, respectively, of the portion of medical device shown in FIG. **133**.

FIGS. **137** and **138** are a side view and a top plan view, respectively, of a portion of a medical device according to an embodiment of the invention.

FIG. **139** is a posterior view of a two spinal implants according to an embodiment of the invention disposed within a body, each disposed between a pair of spinous processes.

FIG. **140** is a posterior view of a portion of a medical device according to an embodiment of the invention disposed within a body between a pair of spinous processes.

FIG. **141** is a cross-sectional side view of the portion of medical device shown in FIG. **140** taken along the line **141-141**.

FIGS. **142** and **143** are a side view and a top plan view, respectively, of a portion of a medical device according to an embodiment of the invention.

FIG. **144** shows a posterior view of a multi-level insertion operation in which a medical device is disposed within a body according to an embodiment of the invention.

FIG. **145** is a flow chart of a method of inserting a spinal implant according to an embodiment of the invention.

FIG. **146** is a flow chart of a method of inserting a spinal implant according to an embodiment of the invention.

DETAILED DESCRIPTION

As used in this specification and the appended claims, the singular forms “a,” “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, the term “a member” is intended to mean a single member or a combination of members, “a material” is intended to mean one or more materials, or a combination thereof. Furthermore, the words “proximal” and “distal” refer to direction closer to and away from, respectively, an operator (e.g., surgeon, physician, nurse, technician, etc.) who would insert the medical device into the patient, with the tip-end (i.e., distal end) of the device inserted inside a patient’s body first. Thus, for example, the implant end first inserted inside the patient’s body would be the distal end of the implant, while the implant end to last enter the patient’s body would be the proximal end of the implant.

In some embodiments, a method includes placement of two or more support members (e.g., spacers, inter-spinous implants, expandable devices, extension limiting devices or the like) at two or more inter-spinous spaces through a single incision. Tools configured to facilitate placement of two or more support members at different locations along the length of the patient’s spine through a single incision are also described herein. In one embodiment, the tools are configured with one or more curvatures such that support members that are introduced through the same incision can be directed towards different inter-spinous locations along the length of a patient’s spine.

In some embodiments, a single incision is made on a patient’s back, lateral to the mid-line of the patient’s body. In some embodiments, the incision can be at least 3 cm lateral to the mid-line. In other embodiments, the incision can be at least 5 cm lateral to the mid-line. In yet other embodiments, the incision can be positioned 6-8 cm lateral to the mid-line. A curved trocar or tunneling device is inserted into the incision to establish a first path to a first location between two adjacent spinous processes. The distal portion of the trocar may be utilized to create an opening between the two adjacent spinous processes for receiving a support member. A first support member is inserted through the first path and placed at the first location. The first support member may be inserted in a compressed state and then expanded to secure it between the two spinous processes. Preferably, a curved instrument is used to carry the support member through the first path and deploy the support member between the two spinous processes. A trocar, which may be the same trocar or a different trocar used to establish the first path, can then be used to establish a second path from the same incision to a second location, one or two levels below or above the first location. Again, the distal portion of the trocar may be utilized to create an opening at the second location between two adjacent spinous processes for receiving a support member. A second support member is inserted through the second path and placed at the second location. The second support member may be inserted in a compressed state and then expanded to secure it between the two spinous processes. Similar to the placement of the first support member, preferably, a curved instrument is used to carry the second support member through the second path and deploy the support member at the second location between two adjacent spinous processes. Optionally, a third path may be established through the same incision to place a third support member at a third location along the length of the patient’s spine. Once the support members are implanted, the surgeon can remove the surgical instrument and close the incision.

In some embodiments, a method includes making an incision in a body, the incision having a size no greater than a distance between a pair of adjacent spinous processes. In some embodiments, for example, the incision can have a size no greater than 50 mm. In other embodiments, the incision can have a size no greater than about 30 mm. In yet other embodiments, the incision can have a size no greater than about 15 mm. A first support member is inserted percutaneously through the incision. The first support member is disposed between a first pair of adjacent spinous processes. A second support member is inserted percutaneously through the incision. The second support member is disposed between a second pair of adjacent spinous processes.

In some embodiments, a method includes making an incision in a body, the incision having a size no greater than approximately one half a distance between a first pair of adjacent spinous processes. A first tool is inserted percutaneously through the incision to define a first passageway extending from the incision to a space between the first pair of adjacent spinous processes. A first support member is disposed, via the first passageway, into the space between the first pair of adjacent spinous processes. A second tool is inserted percutaneously through the incision to define a second passageway extending from the incision to a space between a second pair of adjacent spinous processes. A second support member is disposed, via the second passageway, into the space between the second pair of adjacent spinous processes.

In some embodiments, an apparatus includes an elongate member, such as, for example a rigid shaft. The elongate member has a distal end portion configured to releasably engage a spinal implant. A portion of the elongate member is curved such that the elongate member can insert percutaneously through an incision a first spinal implant between a first pair of adjacent spinous processes and insert percutaneously through the incision a second spinal implant between a second pair of adjacent spinous processes. In some embodiments, the incision can be, for example, a lateral incision having a length of 15 mm or less.

In some embodiments, an apparatus includes an elongate member having a distal end portion and a curved portion. The elongate member, which can be, for example a rigid shaft, is configured to insert percutaneously a spinal implant between a pair of adjacent spinous processes. The distal end portion of the elongate member is configured to releasably engage the spinal implant. The curved portion of the elongate member defines a first radius of curvature about a first axis substantially normal to a center line of the elongate member and a second radius of curvature about a second axis substantially normal to the center line of the elongate member. In some embodiments, a portion of the elongate member is disposed between the first axis and the second axis. In some embodiments, the second axis is substantially normal to the first axis.

In some embodiments, a kit includes a spinal implant and an insertion tool. The spinal implant is reconfigurable between an expanded configuration and a collapsed configuration while disposed between a pair of adjacent spinous processes. The insertion tool is configured to be releasably coupled to the spinal implant. The insertion tool is curved to allow the insertion tool to insert percutaneously through a lateral incision the spinal implant within a space between the pair of adjacent spinous processes, the lateral incision being offset from the space between the pair of adjacent spinous processes.

In some embodiments, a kit includes a first spinal implant, a second spinal implant, a first insertion tool and a second insertion tool. The first and second spinal implants are each reconfigurable between an expanded configuration and a collapsed configuration while disposed between adjacent spinous processes. The first and second insertion tools are each configured to be releasably coupled to a spinal implant. The first insertion tool is configured to insert percutaneously through a lateral incision the first spinal implant within a space between a first pair of adjacent spinous processes. The second insertion tool is configured to insert percutaneously through the same lateral incision the second spinal implant within a space between a second pair of adjacent spinous processes. In some embodiments, the incision can have a length of not greater than 15 mm.

FIG. **1** is a schematic illustration of a medical device according to an embodiment of the invention adjacent two adjacent spinous processes. The medical device **10** includes a proximal portion **12**, a distal portion **14** and a central portion **16**. The medical device **10** has a first configuration in which it can be inserted between adjacent spinous processes S. The central portion **16** is configured to contact the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the central portion **16** does not substantially distract the adjacent spinous processes S. In other embodiments, the central portion **16** does not distract the adjacent spinous processes S.

In the first configuration, the proximal portion **12**, the distal portion **14** and the central portion **16** are coaxial (i.e., share a common longitudinal axis). In some embodiments, the proximal portion **12**, the distal portion **14** and the central portion **16** define a tube having a constant inner diameter. In other embodiments, the proximal portion **12**, the distal portion **14** and the central portion **16** define a tube having a constant outer diameter and/or inner diameter.

The medical device **10** can be moved from the first configuration to a second configuration as illustrated in FIG. **2**. In the second configuration, the proximal portion **12** and the distal portion **14** are positioned to limit lateral movement of the device **10** with respect to the spinous processes S. The proximal portion **12** and the distal portion **14** are configured to engage the spinous process (i.e., either directly or through surrounding tissue) in the second configuration. For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated.

In some embodiments, the proximal portion **12**, the distal portion **14** and the central portion **16** are monolithically formed. In other embodiments, one or more of the proximal portion **12**, the distal portion **14** and the central portion **16** are separate components that can be coupled together to form the medical device **10**. For example, the proximal portion **12** and distal portion **14** can be monolithically formed and the central portion can be a separate component that is coupled thereto.

In use, the spinous processes S can be distracted prior to inserting the medical device **10**. Distraction of spinous processes is discussed below. When the spinous processes are distracted, a trocar can be used to define an access passage for the medical device **10**. In some embodiments, the trocar can be used to define the passage as well as distract the spinous processes S. Once an access passage is defined, the medical device **10** is inserted percutaneously and advanced between the spinous processes, distal end **14** first, until the central portion **16** is located between the spinous processes S. Once the medical device **10** is in place between the spinous processes, the proximal portion **12** and the distal portion **14** are moved to the second configuration, either serially or simultaneously.

In some embodiments, the medical device **10** is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, the size of portions of the implant is expanded after the implant is inserted between the spinous processes. Once expanded, the size of the expanded portions of the implant is greater than the size of the opening. For example, the size of the opening/incision in the skin may be between 3 millimeters in length and 25 millimeters in length. In some embodiments, the size of the implant in the expanded configuration is between 3 and 25 millimeters.

FIG. **3** is a schematic illustration of a deformable element **18** that is representative of the characteristics of, for example, the distal portion **14** of the medical device **10** in a first configuration. The deformable member **18** includes cutouts A, B, C along its length to define weak points that allow the deformable member **18** to deform in a predetermined manner. Depending upon the depth d of the cutouts A, B, C and the width w of the throats T**1**, T**2**, T**3**, the manner in which the deformable member **18** deforms under an applied load can be controlled and varied. Additionally, depending upon the length L between the cutouts A, B, C (i.e., the length of the material between the cutouts) the manner in which the deformable member **18** deforms can be controlled and varied.

FIG. **4** is a schematic illustration of the expansion properties of the deformable member **18** illustrated in FIG. **3**. When a load is applied, for example, in the direction indicated by arrow X, the deformable member **18** deforms in a predetermined manner based on the characteristics of the deformable member **18** as described above. As illustrated in FIG. **4**, the deformable member **18** deforms most at cutouts B and C due to the configuration of the cutout C and the short distance between cutouts B and C. In some embodiments, the length of the deformable member **18** between cutouts B and C is sized to fit adjacent a spinous process.

The deformable member **18** is stiffer at cutout A due to the shallow depth of cutout A. As indicated in FIG. **4**, a smooth transition is defined by the deformable member **18** between cutouts A and B. Such a smooth transition causes less stress on the tissue surrounding a spinous process than a more drastic transition such as between cutouts B and C. The dimensions and configuration of the deformable member **18** can also determine the timing of the deformation at the various cutouts. The weaker (i.e., deeper and wider) cutouts deform before the stronger (i.e., shallower and narrower) cutouts.

FIGS. **5** and **6** illustrate a spinal implant **100** in a first configuration and second configuration, respectively. As shown in FIG. **5**, the spinal implant **100** is collapsed in a first configuration and can be inserted between adjacent spinous processes. The spinal implant **100** has a first expandable portion **110**, a second expandable portion **120** and a central portion **150**. The first expandable portion **110** has a first end **112** and a second end **1140**. The second expandable portion **120** has a first end **122** and a second end **124**. The central portion **150** is coupled between second end **1140** and first end **122**. In some embodiment, the spinal implant **100** is monolithically formed.

The first expandable portion **110**, the second expandable portion **120** and the central portion **150** have a common longitudinal axis A along the length of spinal implant **100**. The central portion **150** can have the same inner diameter as first expandable portion **110** and the second expandable portion **120**. In some embodiments, the outer diameter of the central portion **150** is smaller than the outer diameter of the first expandable portion **110** and the second expandable portion **120**.

In use, spinal implant **100** is inserted percutaneously between adjacent spinous processes. The first expandable portion **110** is inserted first and is moved past the spinous processes until the central portion **150** is positioned between the spinous processes. The outer diameter of the central portion **150** can be slightly smaller than the space between the spinous processes to account for surrounding ligaments and tissue. In some embodiments, the central portion directly contacts the spinous processes between which it is positioned. In some embodiments, the central portion of spinal implant **100** is a fixed size and is not compressible or expandable.

The first expandable portion **110** includes expanding members **115**, **117** and **119**. Between the expanding members **115**, **117**, **119**, openings **111** are defined. As discussed above, the size and shape of the openings **111** influence the manner in which the expanding members **115**, **117**, **119** deform when an axial load is applied. The second expandable portion **120** includes expanding members **125**, **127** and **129**. Between the expanding members **125**, **127**, **129**, openings **121** are defined. As discussed above, the size and shape of the openings **121** influence the manner in which the expanding members **125**, **127**, **129** deform when an axial load is applied.

When an axial load is applied to the spinal implant **100**, the spinal implant **100** expands to a second configuration as illustrated in FIG. **6**. In the second configuration, first end **112** and second end **1140** of the first expandable portion **110** move towards each other and expanding members **115**, **117**, **119** project substantially laterally away from the longitudinal axis A. Likewise, first end **122** and second end **124** of the second expandable portion **120** move towards one another and expanding members **125**, **127**, **129** project laterally away from the longitudinal axis A. The expanding members **115**, **117**, **119**, **125**, **127**, **129** in the second configuration form projections that extend to positions adjacent to the spinous processes between which the spinal implant **100** is inserted. In the second configuration, the expanding members **115**, **117**, **119**, **125**, **127**, **129** inhibit lateral movement of the spinal implant **100**, while the central portion **150** prevents the adjacent spinous processes from moving together any closer than the distance defined by the diameter of the central portion **150**.

A spinal implant **200** according to an embodiment of the invention is illustrated in FIGS. **7-9** in various configurations. Spinal implant **200** is illustrated in a completely collapsed configuration in FIG. **7** and can be inserted between adjacent spinous processes. The spinal implant **200** has a first expandable portion **210**, a second expandable portion **220** and a central portion **250**. The first expandable portion **210** has a first end **212** and a second end **214**. The second expandable portion **220** has a first end **222** and a second end **224**. The central portion **250** is coupled between second end **214** and first end **222**.

The first expandable portion **210**, the second expandable portion **220** and the central portion **250** have a common longitudinal axis A along the length of spinal implant **200**. The central portion **250** can have the same inner diameter as first expandable portion **210** and the second expandable portion **220**. The outer diameter of the central portion **250** is greater than the outer diameter of the first expandable portion **210** and the second expandable portion **220**. The central portion **250** can be monolithically formed with the first expandable portion **210** and the second expandable portion **220** or can be a separately formed sleeve coupled thereto or thereupon.

In use, spinal implant **200** is inserted percutaneously between adjacent spinous processes S. The first expandable portion **210** is inserted first and is moved past the spinous processes S until the central portion **250** is positioned between the spinous processes S. The outer diameter of the central portion **250** can be slightly smaller than the space between the spinous processes S to account for surrounding ligaments and tissue. In some embodiments, the central portion **250** directly contacts the spinous processes S between which it is positioned. In some embodiments, the central portion **250** of spinal implant **200** is a fixed size and is not compressible or expandable. In other embodiments, the central portion **250** can compress to conform to the shape of the spinous processes.

The first expandable portion **210** includes expanding members **215**, **217** and **219**. Between the expanding members **215**, **217**, **219**, openings **211** are defined. As discussed above, the size and shape of the openings **211** influence the manner in which the expanding members **215**, **217**, **219** deform when an axial load is applied. Each expanding member **215**, **217**, **219** of the first expandable portion **210** includes a tab **213** extending into the opening **211** and an opposing mating slot **218**. In some embodiments, the first end **212** of the first expandable portion **210** is rounded to facilitate insertion of the spinal implant **200**.

The second expandable portion **220** includes expanding members **225**, **227** and **229**. Between the expanding members **225**, **227**, **229**, openings **221** are defined. As discussed above, the size and shape of the openings **221** influence the manner in which the expanding members **225**, **227**, **229** deform when an axial load is applied. Each expanding member **225**, **227**, **229** of the second expandable portion **220** includes a tab **223** extending into the opening **221** and an opposing mating slot **228**.

When an axial load is applied to the spinal implant **200**, the spinal implant moves to a partially expanded configuration as illustrated in FIG. **8**. In the partially expanded configuration, first end **222** and second end **224** of the second expandable portion **220** move towards one another and expanding members **225**, **227**, **229** project laterally away from the longitudinal axis A. To prevent the second expandable portion **220** from over-expanding, the tab **223** engages slot **228** and acts as a positive stop. As the axial load continues to be imparted to the spinal implant **200** after the tab **223** engages slot **228**, the load is transferred to the first expandable portion **210**. Accordingly, the first end **212** and the second end **214** then move towards one another until tab **213** engages slot **218** in the fully expanded configuration illustrated in FIG. **9**. In the second configuration, expanding members **215**, **217**, **219** project laterally away from the longitudinal axis A. In some alternative embodiments, the first expandable portion and the second expandable portion expand simultaneously under an axial load.

The order of expansion of the spinal implant **200** can be controlled by varying the size of openings **211** and **221**. For example, in the embodiments shown in FIGS. **7-9**, the opening **221** is slightly larger than the opening **211**. Accordingly, the notches **226** are slightly larger than the notches **216**. As discussed above with respect to FIGS. **3** and **4**, for this reason, the second expandable portion **220** will expand before the first expandable portion **210** under an axial load.

In the second configuration, the expanding members **215**, **217**, **219**, **225**, **227**, **229** form projections that extend adjacent the spinous processes S. Once in the second configuration, the expanding members **215**, **217**, **219**, **225**, **227**, **229** inhibit lateral movement of the spinal implant **200**, while the central portion **250** prevents the adjacent spinous processes from moving together any closer than the distance defined by the diameter of the central portion **250**.

The portion P of each of the expanding members **215**, **217**, **219**, **225**, **227**, **229** proximal to the spinous process S expands such that portion P is substantially parallel to the spinous process S. The portion D of each of the expanding members **215**, **217**, **219**, **225**, **227**, **229** distal from the spinous process S is angled such that less tension is imparted to the surrounding tissue.

In the second configuration, the expanding members **225**, **227**, **229** are separate by approximately 120 degrees from an axial view as illustrated in FIG. **10**. While three expanding members are illustrated, two or more expanding members may be used and arranged in an overlapping or interleaved fashion when multiple implants **200** are inserted between multiple adjacent spinous processes. Additionally, regardless of the number of expanding members provided, the adjacent expanding members need not be separated by equal angles or distances.

The spinal implant **200** is deformed by a compressive force imparted substantially along the longitudinal axis A of the spinal implant **200**. The compressive force is imparted, for example, by attaching a rod (not illustrated) to the first end **212** of the first expandable portion **210** and drawing the rod along the longitudinal axis while imparting an opposing force against the second end **224** of the second expandable portion **220**. The opposing forces result in a compressive force causing the spinal implant **200** to expand as discussed above.

The rod used to impart compressive force to the spinal implant **200** can be removably coupled to the spinal implant **200**. For example, the spinal implant **200** can include threads **208** at the first end **212** of the first expandable portion **210**. The force opposing that imparted by the rod can be applied by using a push bar (not illustrated) that is removably coupled to the second end **224** of the second expandable portion **220**. The push rod can be aligned with the spinal implant **200** by an alignment notch **206** at the second end **224**. The spinal implant **200** can also be deformed in a variety of other ways, examples of which are discussed in detail below.

FIGS. **11-14** illustrate a spinal implant **300** according to an embodiment of the invention. Spinal implant **300** includes an elongated tube **310** configured to be positioned between adjacent spinous processes S and having a first end **312** and a second end **314**. The elongated tube **310** has longitudinal slots **311** defined along its length at predetermined locations. The slots **311** are configured to allow portions of the elongated tube **310** to expand outwardly to form projections **317**. An inflatable member **350** is disposed about the elongated tube between adjacent sets of slots **311**.

The inflatable member **350** is configured to be positioned between adjacent spinous processes S as illustrated in FIGS. **11-14**. Once inserted between the adjacent spinous processes, the inflatable member **350** is inflated with a liquid and/or a gas, which can be, for example, a biocompatible material. The inflatable member **350** is inflated to maintain the spinal implant **300** in position between the spinous processes S. In some embodiments, the inflatable member **350** is configured to at least partially distract the spinous processes S when inflated. The inflatable member **350** can be inflated to varied dimensions to account for different spacing between spinous processes S.

The inflatable member **350** can be inflated via an inflation tube **370** inserted through the spinal implant **300** once spinal implant **300** is in position between the spinous processes S. Either before or after the inflatable member **350** is inflated, the projections **317** are expanded. To expand the projections **317**, an axial force is applied to the spinal implant **300** using draw bar **320**, which is coupled to the first end **312** of the spinal implant **300**.

As the draw bar **320** is pulled, the axial load causes the projections **317** to buckle outwardly, thereby preventing the spinal implant from lateral movement with respect to the spinous processes S. FIG. **12** is an illustration of the spinal implant **300** during deformation, the projections **317** being only partially formed. Although illustrated as deforming simultaneously, the slots **311** alternatively can be dimensioned such that the deformation occurs at different times as described above. Once the spinal implant is in the expanded configuration (see FIG. **13**), the draw bar **320** is removed from the elongated tube **310**.

The orientation of the spinal implant **300** need not be such that two projections are substantially parallel to the axis of the portion of the spine to which they are adjacent as illustrated in FIG. **14**. For example, the spinal implant **300** can be oriented such that each of the projections **317** is at a 45 degree angle with respect to the spinal axis.

The spinal implants **100**, **200**, **300** can be deformed from their first configuration to their second configuration using a variety of expansion devices. For example, portions of the spinal implants **100**, **200**, **300**, as well as other types of implants I, can be deformed using expansion devices described below. While various types of implants I are illustrated, the various expansion devices described can be used with any of the implants described herein.

FIGS. **15-17** illustrate an embodiment of an expansion device **1500** (also referred to herein as an insertion tool or a deployment tool). The expansion device **1500** includes a guide handle **1510**, a knob assembly **1515**, a shaft **1520**, a rod **1570** and an implant support portion **1530**. The expansion device **1500** is used to insert an implant (not illustrated) in between adjacent spinous processes and expand the implant such that it is maintained in position between the spinous processes as described above. Both the guide handle **1510** and the knob assembly **1515** can be grasped to manipulate the expansion device **1500** to insert the implant. As described in more detail herein, the knob assembly **1515** is configured such that as the knob assembly **1515** is actuated, the rod **1570** translates and/or rotates within the shaft **1520**; when the rod **1570** translates, the implant (not illustrated) is moved between its collapsed configuration and its expanded configuration; when the rod **1570** rotates, the implant is disengaged from the rod **1570**. While no particular implant is illustrated in FIGS. **15-17**, for purposes of clarity, an implant such as, for example, implant **200** (see FIG. **7**) can be used with the expansion device **1500**.

As best illustrated in FIG. **15**B, the implant support portion **1530** includes a receiving member **1538** and a spacer **1532**. The receiving member **1538** includes a side wall **1540** that is coupled to and supported by the distal end of the shaft **1520**. The side wall **1540** defines an alignment protrusion **1536** and a receiving area **1542** configured to receive a portion of the spacer **1532**. The implant slides over spacer **1532** until its proximal end is received within a recess **1534** defined by the side wall **1540** and the outer surface of the spacer **1532**. The alignment protrusion **1536** is configured to mate with a corresponding notch on the implant (see, e.g., alignment notch **206** in FIG. **7**) to align the implant with respect to the expansion device. Once the implant is aligned within the implant support portion **1530**, the distal end of the implant is threadedly coupled to the distal end of rod **1570**.

As illustrated, the spacer **1532** ensures that the implant is aligned longitudinally during the insertion and expansion process. The spacer **1532** can also be configured to maintain the shape of the implant during insertion and to prevent the expandable portions of the implant from extending inwardly during deployment of the implant. For example, in some embodiments, the spacer **1532** can be constructed from a solid, substantially rigid material, such as stainless steel, having an outer diameter and length corresponding to the inner diameter and length of the implant. In other embodiments, the expansion device can be configured to be used with implants that include an inner core configured to provide structural support to the implant (see, for example, FIGS. **118-124**). In such embodiments, as described in more detail herein, the spacer of the insertion tool can be configured to cooperate with the inner core of the implant to provide the alignment and structural support of the implant during insertion and expansion.

The knob assembly **1515** includes an upper housing **1517** that threadedly receives the shaft **1520**, an actuator knob **1550** and a release knob **1560** as best illustrated in FIG. **15**A. Upper housing **1517** includes internal threads **1519** that mate with external threads **1521** on shaft **1520**. The proximal end of rod **1570** is coupled to the knob assembly **1515** by an adapter **1554**, which is supported by two thrust bearings **1552**. Actuator knob **1550** is coupled to the upper housing **1517** and is engaged with the adapter **1554** such that when actuator knob **1550** is turned in the direction indicated by arrows E (see FIG. **17**), the rod **1570** translates axially relative to the shaft **1520** towards the proximal end of the device **1500**, thereby acting as a draw bar and opposing the movement of the implant in the distal direction. In other words, when the implant is inserted between adjacent spinous processes and the actuator knob **1515** is turned, the distal end of the implant support portion **1530** imparts an axial force against the proximal end of the implant, while the rod **1570** causes an opposing force in the proximal direction. In this manner, the forces imparted by the implant support portion and the rod **1570** cause portions of the implant to expand in a transverse configuration such that the implant is maintained in position between the spinous processes as described above. The expansion device **1500** can also be used to move the implant from its expanded configuration to its collapsed configuration by turning the actuator knob **1550** in the opposite direction.

Once the implant is in position and fully expanded, the release knob **1560** is turned in the direction indicated by arrow R (see FIG. **17**) thereby causing the rod **1570** to rotate within the shaft **1520**. In this manner, the implant can be disengaged from the rod **1570**. During this operation, the implant is prevented from rotating by the alignment protrusion **1536**, which is configured to mate with a corresponding notch on the implant. Once the implant is decoupled from the rod **1570**, the expansion tool **1500** can then be removed from the patient.

Although the knob assembly **1515** is shown and described as including an actuator knob **1550** and a release knob **1560** that are coaxially arranged with a portion of the release knob **1560** being disposed within the actuator knob **1550**, in some embodiments, the release knob is disposed apart from the actuator knob. In other embodiments, the release knob and the actuator knob are not coaxially located. In yet other embodiments, the knob assembly **1515** does not include knobs having a circular shape, but rather includes levers, handles or any other device suitable for actuating the rod relative to the shaft as described above.

FIG. **18** illustrates a portion of expansion device **400** in a collapsed configuration. Expansion device **400** can be used to selectively form protrusions on the implant I (not illustrated in FIG. **18**) at desired locations. The expansion device **400** includes a guide shaft **410**, which can guide the expansion device **400** into the implant I and a cam actuator **450** mounted thereto and positionable into an eccentric position. The expansion device **400** has a longitudinal axis A and the cam actuator **450** has a cam axis C that is laterally offset from the longitudinal axis A by a distance d. FIG. **19** illustrates the expansion device **400** in the expanded configuration with the cam actuator **450** having been rotated about the cam axis C.

The expansion device **400** can be inserted into an implant I through an implant holder H as illustrated in FIG. **20**. The implant holder H is coupled to the implant and is configured to hold the implant in position while the expansion device **400** is being manipulated to deform the implant I. Once the implant I is satisfactorily deformed, the implant holder H can be detached from the implant I and removed from the patient, leaving the implant I behind.

Referring to FIGS. **20** and **21**, the expansion device **400** includes a handle **420** that is used to deploy the cam actuator **450**. When the handle **420** is rotated, the cam actuator **450** is deployed and deforms the implant I. Once the cam actuator **450** is fully deployed (e.g., 180 degrees from its original position) and locked in place, the entire expansion device **400** is rotated to deform the implant I around the circumference of implant I. The cam actuator **450** circumscribes a locus of points that is outside the original diameter of the implant I, forming the projection P (see FIG. **22**). The expansion device **400** can be rotated either by grasping the guide shaft **410** or by using the handle **420** after it has been locked in place.

The expansion device **400** can be used to form multiple projections P. Once a first projection P is formed, the cam actuator **450** can be rotated back to its first configuration and the expansion device **400** advanced through the implant I to a second position. When the expansion device **400** is appropriately positioned, the cam actuator **450** can again be deployed and the expansion device **400** rotated to form a second projection P (see FIG. **23**). In some embodiments, the implant I is positioned between adjacent spinous processes and the projections P are formed on the sides of the spinous processes to prevent lateral (i.e., axial) displacement of the implant I.

An alternative expansion device **500** is illustrated in FIGS. **24** and **25**. FIG. **24** illustrates the expansion device **500** in a first configuration and FIG. **25** illustrates the expansion device **500** in a second configuration. The expansion device **500** includes a guide shaft **510** that is inserted into an implant I. An axial cam shaft actuator **520** is slidably disposed within the guide shaft **520**. The axial cam shaft actuator **520** has a sloped recess **530** to receive a movable object **550**. When the cam shaft actuator **520** is moved, the movable object **550** is displaced along the sloped recess **530** until it protrudes through an opening **540** in the guide shaft **510**.

The movable object **550** is configured to displace a portion of the implant I, thereby forming a projection P. Multiple movable objects **550** can be used around the circumference of the guide shaft **510** to form a radially extending protrusions P around the circumference of the implant I. Additionally, the protrusions can be formed at multiple locations along the length of the implant I by advancing the expansion device **500** along the length of the implant to a second position as discussed above. Alternatively, the expansion device can have multiple recesses that displace other sets of movable objects.

In alternative embodiments, the expansion device can also serve as an implant. For example, the expansion device **500** can be inserted between adjacent spinous processes S, the movable objects moved out through openings **540**, and the expansion device **500** left behind in the body. In such an embodiment, the movable objects prevent the expansion device **500** from lateral movement with respect to the spinous processes S.

In another alternative embodiment, rather than having openings **540** in the expansion device **500**, the movable objects **550** can be positioned against a weaker (e.g., thinner) portion of the wall of the expansion device and move that portion of the expansion device **500** to a protruded configuration.

Another alternative expansion device **600** is illustrated in FIGS. **26**-**28**. FIG. **26** illustrates the expansion device **600** in a first configuration and FIG. **28** illustrates the expansion device in a second configuration. The expansion device **600** includes a guide shaft **610** that is inserted into an implant I. The guide shaft **610** has openings **640** defined therein. An axial cam shaft actuator **620** is rotatably coupled within the guide shaft **610**. Displaceable objects **650** are positioned within the guide shaft **610** and are configured to protrude through the openings **640** in the guide shaft **610**. When the cam shaft actuator **620** is rotated approximately 90 degrees, the movable objects **650** move through the openings **640** and deform the implant I, forming the projection P. Alternatively, the expansion device can have multiple cams that displace other sets of movable objects.

Multiple movable objects **650** can be used around the circumference of the guide shaft **610** to form radially extending protrusions P around the implant I. Additionally, the protrusions can be formed at multiple locations along the length of the implant I by advancing the expansion device **600** along the length of the implant I to a second position as discussed above.

An implant expansion device **700** is illustrated in FIGS. **29** and **30**. The implant expansion device **700** is configured to be inserted into an implant I. The implant **700** includes a guide shaft **710** coupled to a housing **770**. A cam actuator **720** is rotatably mounted within the housing **770** and includes arms **790** that extend in opposite directions from one another. The cam actuator **720** is rotated using rod **722**.

As the cam actuator **720** rotates, the arms **790** engage movable objects **750**. The movable objects **750** are configured to project out of the housing **770** when the cam actuator is rotated in a clockwise manner. Once the movable objects **750** are fully extended, they engage the implant I and the expansion device **700** can be rotated a complete revolution to form a protrusion in the implant I.

After one protrusion is formed, the rod **722** can be rotated counterclockwise to disengage the movable objects **750** from the implant I. Once disengaged, the expansion device **700** can be advanced to another location within the implant I as discussed above.

In some other embodiments, the implant I can be balloon actuated. FIG. **31** illustrates an implant I positioned between adjacent spinous processes S. A balloon actuator **800** in inserted into the implant I and expanded as illustrated in FIG. **32** to move the implant I to its expanded configuration. Once expanded, the balloon actuator **800** can be deflated and removed, leaving the implant I in an expanded configuration.

In some embodiments, the balloon actuator **800** can have multiple lobes, one that expands on each side of the spinous process S. In other embodiments, multiple balloon actuators **800** can be used to expand the implant I.

FIG. **33** is a cross-sectional view of an expandable implant **900** that can be expanded using an expansion device **950**, illustrated in FIGS. **34**-**37**. The implant **900** has an elongated body portion **910** having a first end **901** and a second end **902**. The first end **901** has an externally threaded portion **911** and the second end **902** has an internally threaded portion **912**. The implant **900** has a first outer diameter D**1** at the externally threaded portion **911** and a second outer diameter D**2**, which wider than the first outer diameter D**1**.

The expansion device **950** includes a draw bar **960** and a compression bar **970**. In some embodiments, the compression bar **970** defines a channel **975** having internal threads **971** to mate with the externally threaded portion **911** of the implant **900** (see FIG. **34**). The draw bar **960** has external threads **961** to mate with the internally threaded portion **912** of implant **900**.

In use, the compression bar **970** is coupled to the first end **901** of the implant **900** and abuts the implant **900** at the transition between the first outer diameter D**1** and the second outer diameter D**2**, which serves as a stop for the compression bar **970**. In some embodiments, the outer diameter of the entire implant **900** is substantially constant and the inner diameter of the compression bar **970** narrows to serve as the stop for the compression bar **970**. With the compression bar **970** in place, the draw bar **960** is inserted through the channel **975** and is coupled to the second end **902** of the implant **900** via the internally threaded portion **912** of implant **900** (see FIG. **35**). Once the compression bar **970** and the draw bar **960** are coupled to the implant **900**, the draw bar **960** can be pulled while imparting an opposing force on the compression bar **970** to expand the implant **900** (see FIG. **36**). When the implant **900** is fully expanded, the compression bar **970** and the draw bar **960** are removed and the implant is left behind in the body.

With the expansion devices described herein, the location of protrusions can be selected in vivo, rather than having predetermined expansion locations. Such a configuration reduces the need to have multiple sizes of spacers available. Additionally, the timing of the deployment of the protrusions can be varied.

The various implants **100**, **200**, **300** described herein can be made from, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, etc. The material can have a tensile strength similar to or higher than that of bone.

In other embodiments of the invention, an apparatus includes a first clamp having a first end and a second end. The second end of the first clamp is configured to engage a first spinous process. A second clamp has a first end and a second end. The second end of the second clamp is configured to engage a second spinous process spaced apart from the first spinous process. A connector is coupled to the first end of the first clamp and the first end of the second clamp.

FIG. **38** is a schematic illustration of a medical device according to an embodiment of the invention attached to two adjacent spinous processes. The apparatus **1010** includes a first clamp **1012** configured to be coupled to a first spinous process S and a second clamp **1014** configured to be coupled to a second spinous process S. The first clamp **1012** and the second clamp **1014** are configured to be moved apart from one another in the direction indicated by arrows X. As the first clamp **1012** and the second clamp **1014** are moved apart, an opening between adjacent spinous processes S expands. An insert **1050** can be inserted between the spinous processes S in the direction indicated by arrow Y to maintain the opening between the spinous processes S. The clamps **1012**, **1014** engage the spinous processes S with sufficient force such that when the clamps **1012**, **1014** are spread apart, they cause lateral displacement of the spinous processes S.

FIG. **39** is a side view of a medical device according to an embodiment of the invention coupled to a portion of a spine. The tissue surrounding the spine is not illustrated for the sake of clarity. The medical device **1000** includes a first clamp **1100** and a second clamp **1200**. The first clamp **1100** has a proximal end **1120** and a distal end **1140**. The distal end **1140** of the first clamp **1100** is configured to engage a first spinous process S. The second clamp **1200** has a first end **1220** and a second end **1240**. The second end **1240** of the second clamp **1200** is configured to engage a second spinous process S that is spaced apart from the first spinous process S.

A connector **1300** is coupled to the proximal end **1120** of the first clamp **1100** and the first end **1220** of the second clamp **1200**. The position of the connector **1300** relative to the first clamp **1100** and the second clamp **1200** can be adjusted such that the distance between the first clamp **1100** and the second clamp **1200** can be adjusted. In other words, the connector **1300** is reconfigurable between a first configuration and a second configuration. The first clamp **1100** is a first distance from the second clamp **1200** when the connector **1300** is in its first configuration and is a second distance from the second clamp **1200** when the connector **1300** is in its second configuration.

Referring to FIG. **40**, in which the first clamp **1100** is illustrated, the first clamp **1100** includes a first jaw **1150** and a second jaw **1130** opposite the first jaw **1150**. The first jaw **1150** and the second jaw **1130** are configured to be movable between a first configuration and a second configuration. The first jaw **1150** and the second jaw **1130** are closer together in the second configuration than in the first configuration. In the second configuration, the first jaw **1150** and the second jaw **1130** engage the spinous process S with sufficient force to substantially maintain the orientation of the first clamp **1100** and the second clamp **1200** with respect to the spinous process S when the connector **1300** is moved to its second configuration, thereby spreading the spinous processes S. The second clamp **1200** has a similar configuration, but is not illustrated for ease of reference. The material of the jaws **1150**, **1130** are such that they can sufficiently engage the spinous processes S as described, but to not damage the spinous processes. Adequate materials include, for example, stainless steel, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, etc. The material can have a tensile strength similar to or higher than that of bone. In some embodiments, the clamp **1200** can be manufactured from stainless steel and a coating and/or an over-mold or over-layer of PEEK or carbon fiber can be applied to the jaws **1150**, **1130**.

In some embodiments, the medical device **100** is used to spread adjacent spinous processes of severely compressed vertebrae. Additionally, the medical device **100** stabilizes the spinous processes during procedures without penetrating the vertebrae.

In some embodiments, the first clamp **1100** includes a first arm **1170** and a second arm **1180** and a tension member **1160**. The first arm **1170** and second arm **1180** can be resiliently coupled such that as tension member **1160** is advanced towards the distal end **1140** of the clamp **1100**, the first arm **1170** and the second arm **1180** are moved towards one another, but as the tension member **1160** is moved away from the distal end **1140** of the clamp **1100**, the first arm **1170** and the second arm **1180** return to their default position (i.e., spaced apart).

The tension member **1160** is configured to move the first jaw **1150** and the second jaw **1130** between their first configuration and their second configuration as the first arm **1170** and the second arm **1180** move towards one another. As the tension member **1160** is moved towards the first jaw **1150** and the second jaw **1130**, the first jaw **1150** and the second jaw **1130** engage the spinous process S. In some applications, a distal end **1140** of the clamp **1100** is positioned adjacent the lamina L of the vertebra to which it is coupled. In some embodiments, the clamp **1100** is attached close to the lamina L to minimize the lever arm on the spinous process. The distal end **1140** of clamp **1100** need not penetrate the lamina L.

In an alternative embodiment, the tension member includes threads that engage threads on the first clamp. In such an embodiment, the tension member is moved along the length of the first clamp by turning the tension member. Returning to FIG. **40**, the tension member **1160** may optionally include a tapered portion **1190** that matingly engages a tapered portion **1110** of first clamp **1100**. Such a configuration can ensure appropriate distribution of the forces to the spinous process S. The second clamp **1200** is similarly configured and includes a tension member **126** and opposing jaws.

A swing arm **1700** is pivotably coupled to the connector **1300** between the first clamp **1100** and the second clamp **1200**. The swing arm **1700** has an arcuate portion **173** and travels along a range of motion. The arcuate portion **173** of the swing arm **1700** has a first end **1750** and a second end **1770**.

As best seen in FIGS. **41** and **42**, the second end **1770** of the arcuate portion **173** of swing arm **1700** is configured to receive a working tool **1840**, such as, for example, a pointed trocar tip. The swing arm **1700** defines an opening **1740** in which at least a portion of the working tool **1840** is received. In some embodiments, the opening **1740** extends along the entire length of the arcuate portion **173** between the first end **1750** and the second end **1770**. In some embodiments, an optional handle **190** can be coupled to the first clamp **1100** and/or the second clamp **1200** to facilitate insertion of the clamps **1100**, **1200** and increase stability of the apparatus **1000** during use.

The working tool **1840** is coupled to a guide wire **1860**. The guide wire **1860** has a first end **1810** and a second end **1830**. The second end **1830** of the guide wire **1860** is coupled to the working tool **1840**. A retainer **1820** (discussed in detail below) is coupled to the first end **1810** of the guide wire **1860** and is configured to maintain the position of the working tool **1840** with respect to the swing arm **1700**. The retainer **1820** is matingly received in a recess **1720** in the swing arm **1700**. The guide wire **1860** is received in the opening **1740** defined in the swing arm **1700**. The guide wire is received in the opening

1740 through a channel **1760** defined in the swing arm **1700** as best seen in FIG. **43**. In some alternative embodiments, the guide wire does not extend through the opening **1740** of the swing arm **1700**. In yet other alternative embodiments, the guide wire is not present.

FIGS. **44** and **45** illustrate the retainer **1820** in a first configuration and a second configuration, respectively. The retainer **1820** includes a housing **1880** that defines an opening **1870** through which guide wire **1860** is movably disposed. The guide wire **1860** is coupled to a retention member **1830**. The retention member **1830** is biased towards a first end **1890** of housing **1880** by a spring **1850**. The spring **1850** is between a second end **1810** of the housing **1880** and the retention member **1830**.

In use, when the retainer **1850** is in the first configuration (FIG. **44**), the working tool is maintained in the swing arm **1700**. When the retainer **1820** is moved to its second configuration (FIG. **45**), the working tool **1840** can be removed from the swing arm **1700**. When moved to the second configuration, the retainer **1820** is displaced a distance d, thereby increasing the effective length of the guide wire **1860**, allowing movement of the working tool **1840** with respect to the end of the swing arm **1700**. In some embodiments, the distance d is approximately the same as the length of the portion of the working tool **1840** received in the swing arm **1700**.

As shown in FIG. **46**, a working tool **1840'** is inserted into an opening **1740'** defined by a swing arm **1700'**. The swing arm **1700'** includes a projection **1920** within opening **1740'** that mates with a recess **1970** on working tool **1840'**.

Returning to FIGS. **39-42**, in use, a first clamp **1100** is inserted through a body B and coupled to a spinous process S. The tension member **1160** is moved towards the distal end **1140** of the first clamp to engage the first jaw **1150** and the second jaw **1130** with the spinous process S. The second clamp **1200** is then inserted and similarly coupled to the adjacent spinous process S. The connector **1300** is actuated to increase the distance between the first clamp **1100** and the second clamp **1200**, thereby separating the adjacent spinous processes S. Once the spinous processes S are separated, the swing arm **1700** is moved through its range of motion M.

The swing arm **1700** is moved from a location outside a body B through a range of motion M (see, e.g., FIG. **41**). The swing arm **1700** enters the body B and moves through range of motion M until it is at target T (see, e.g., FIG. **39**) between adjacent spinous processes S.

The movement of the swing arm **1700** into the body defines a path within the tissue (not illustrated). The tissue is penetrated by a pointed projection (i.e., working tool **1840**). The path M defined by the swing arm **1700** includes the target T between the adjacent spinous processes S. Once the path is defined, the swing arm **1700** can be removed and a spacer **500** (see FIG. **49**), discussed in detail below, can be inserted between the adjacent spinous processes S. In some embodiments of the invention, the spacer **5000** can be removably attached to the swing arm **1700**, inserted into the body and then removed from the swing arm **1700**.

A medical device **2000** according to an embodiment of the invention is illustrated in FIG. **47**. Medical device **2000** includes a handle **2900** coupled to an arm **2700**. The arm **2700** has a first end **2750** and a second end **2770** and defines an opening **2740** along its length. A working tool **2840** can be received within opening **2740** adjacent the second end **2770**. The arm **2700** also includes a recess **2720** to receive a retainer (not illustrated) similar to retainer **1850** discussed above. Medical device **2000** is inserted between adjacent spinous process in a manner similar to swing arm **1700** discussed above. The depth and placement of the arm **2700**, however is determined by the user of the medical device **2000**. Such a medical device can be used with or without the benefit of the clamps **1100**, **1200** discussed above. In other words, the medical device **2000** can be inserted between adjacent spinous processes S without first separating the spinous processes S.

A medical device according to another embodiment of the invention is illustrated in FIG. **48**. Medical device **2010** is a distraction tool having a handle **2011**, a curved shaft **2020** and a distraction portion **2030**. The distraction portion **2030** includes a pointed tip **2032** and an insertion position indicator **2034**. The medical device **2010** is inserted into a patient's back and moved in between adjacent spinous processes from the side of the spinous processes (i.e., a posterior-lateral approach). The configuration of the curved shaft **2020** assists in the use of a lateral approach to the spinous processes. The distraction portion **2030** defines a path through the patient's tissue and between the adjacent spinous processes.

The position indicator **2034** can be a physical ridge or detent such that the physician can identify through tactile sensation when the medical device **2010** has been inserted an appropriate distance (e.g., when the position indicator **2034** engages the spinous processes). The position indicator **2034** can alternatively be a radioopaque strip that can be imaged using a fluoroscope. As a further alternative, multiple fluoroscopic markings (not illustrated) can be placed on the shaft **2020** within the distraction portion **2030**. The markings can be imaged to determine the spacing between the spinous processes and/or the position of the distraction portion **2030** relative to the spinous processes. Once the spinous processes are adequately distracted, the medical device **2010** is removed. After the medical device **2010** is removed, an implant (not illustrated in FIG. **48**) is positioned between spinous processes using an insertion tool to limit the minimum distance between the spinous processes during their range of motion.

An alternative swing arm **1700"** for use with medical device **100** according to an embodiment of the invention is illustrated in FIGS. **49***a*-**49***c*. As best seen in FIGS. **49***a* and **45***c*, the second end **1770"** of swing arm **1700"** is configured to receive a working tool **1840"**, such as, for example, a pointed trocar tip. The swing arm **1700"** defines an opening **1740"** in which at least a portion of the working tool **1840"** is received. In some embodiments, the opening **1740"** extends along the entire length of the swing arm **1700"** between the first end **1750"** and the second end **1770"** to define a passageway or lumen. The opening **1740"** is slightly larger than the diameter of the working tool **1840"** such that the working tool **1840"** is positioned within the opening **1740"** during use.

The working tool **1840"** is coupled to a wire **1860"**. The wire **1860"** has a first end **1810"** and a second end **1830"**. The second end **1830"** of the wire **1860"** is coupled to the working tool **1840"**. A retainer **1820"** (discussed in detail below) is coupled to the first end **1810"** of the wire **1860"** and is configured to maintain the position of the working tool **1840"** with respect to the swing arm **1700"**. In some embodiments, the wire **1860"** is substantially rigid such that the working tool **1840"** is not retracted into the opening **1740"** when force is imparted against the working tool **1840"**.

The retainer **1820"** is received in a recess **1720"** in the swing arm **1700"**. The retainer **1820"** is maintained in the recess **1720"** using threaded fasteners **173"**. In some alternative embodiments, the wire **1860"** does not extend through the opening **1740"** of the swing arm **1700"**. In yet other alternative embodiments, the wire **1860"** is not present.

FIGS. **50-59** illustrate various spacers **5000** that can be inserted between adjacent spinous processes S. Once the spacer **5000** is inserted between the spinous processes S, depending upon the type of spacer **5000**, the spacer **5000** can be deformed to be held in place. For example, in some embodiments, a balloon actuator **5500** can be inserted into the spacer and expanded, thereby expanding the ends of the spacer **5000** to retain the spacer **5000** between the spinous processes S (see, e.g., FIGS. **50**, **52** and **56**). Once the spacer **5000** is expanded, the balloon actuator **5500** can be deflated and removed (see, e.g., FIG. **57**).

In some embodiments of the invention, the spacer **5000** includes an end portion **5750** that includes a recess **5970** that is configured to mate with the projection **1920** on swing arm **1700'** (see FIG. **46**).

In another embodiment, a method includes percutaneously inserting into a body an expandable member having a first configuration, a second configuration and a third configuration. The expandable member includes a support portion and a retention portion. The support portion has a longitudinal axis and is configured to be disposed between adjacent spinous processes. The retention portion is configured to limit movement of the support portion along the longitudinal axis. When the expandable member is in the first configuration, it is disposed in a first location between the adjacent spinous processes. The expandable member is then expanded from the first configuration to the second configuration. The expandable member is then contracted from the second configuration to the third configuration and disposed in a second location, the second location being different from the first location.

In some embodiments, an apparatus includes an expandable member having a support portion, a retention portion, a first configuration, and a second configuration. The support portion has a longitudinal axis and is configured to be disposed between adjacent spinous processes. The retention portion is disposed adjacent to the support portion and is configured to limit movement of the support portion along the longitudinal axis. When in the first configuration, the expandable member has a first volume. When in the second configuration, the expandable member has a second volume, the second volume being greater than the first volume. The expandable member is configured to move from the first configuration to the second configuration and to move from the second configuration to the first configuration.

In some embodiments, the apparatus includes a sensor coupled to the expandable member. The sensor can be, for example, a strain gauge sensor or a piezoelectric sensor that measures a force applied to the expandable member and/or a pressure of a fluid within the expandable member.

In some embodiments, an apparatus includes a substantially rigid support member, a first expandable member and a second expandable member. The support member is configured to be disposed between adjacent spinous processes. The first expandable member is coupled to a proximal portion of the support member and has a first configuration in which it has a first volume and a second configuration in which it has a second volume, which is greater than the first volume. Similarly, the second expandable member is coupled to a distal portion of the support member and has a first configuration in which it has a first volume and a second configuration in which it has a second volume, which is greater than the first volume.

FIGS. **60**A-**60**D are schematic illustrations of a posterior view of a medical device **4000** according to an embodiment of the invention positioned adjacent two adjacent spinous processes S in a first configuration (FIG. **60**A), a second configuration (FIGS. **60**B and **60**D) and a third configuration (FIG. **60**C). The medical device **4000** includes an expandable member **4002** having an inner area (not shown) and an outer surface **4010**. The outer surface **4010** is configured to be disposed between the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the expandable member **4002** distracts the adjacent spinous processes S. In other embodiments, the expandable member **4002** does not distract the adjacent spinous processes S.

The expandable member **4002** has a first configuration, a second configuration and a third configuration. When in each configuration, the expandable member **4002** has an associated volume. As illustrated in FIG. **60**A, the first configuration represents a substantially contracted condition in which the expandable member **4002** has a minimal volume. When the expandable member **4002** is in the first configuration, the medical device **4000** is inserted between the adjacent spinous processes S. As illustrated in FIGS. **60**B and **60**D, the second configuration represents an expanded condition in which the expandable member **4002** has a large volume. When the expandable member **4002** is in the second configuration, the outer surface **4010** of the medical device **4000** contacts the adjacent spinous processes S during at least a portion of the range of motion of the spinous processes. As illustrated in FIG. **60**C, the third configuration represents a partially expanded condition in which the expandable member **4002** has a volume between that associated with the first configuration and that associated with the second configuration. When the expandable member **4002** is in the third configuration, the medical device **4000** can be repositioned between the adjacent spinous processes, as indicated by the arrow in FIG. **60**C. The medical device can then be subsequently re-expanded into the second configuration, as illustrated in FIG. **60**D.

FIGS. **61**A-**61**C are schematic illustrations of a posterior view of the medical device **4000** positioned adjacent two adjacent spinous processes S in a first configuration, a second configuration and a third configuration, respectively. As described above, when the expandable member **4002** is in the first configuration, the medical device **4000** is inserted between the adjacent spinous processes S. The expandable member **4002** is then expanded to the second configuration, in which the outer surface **4010** of the medical device **4000** is disposed between the adjacent spinous processes S. The expandable member **4002** is then contracted to the third configuration to facilitate removal of the medical device **4000**, as shown in FIG. **61**C. In some embodiments, the third configuration can be the same as the first configuration.

In use, the adjacent spinous processes S can be distracted prior to inserting the medical device **4000** into a body. Distraction of spinous processes described herein. When the spinous processes S are distracted, a trocar (not shown) can be used to define an access passageway (not shown) for the medical device **4000**. In some embodiments, the trocar can be used to define the passage as well as to distract the spinous processes S. Once an access passageway is defined, the medical device **4000** is inserted percutaneously and advanced between the spinous processes S and placed in the desired position between the adjacent spinous processes S. Once the medical device **4000** is in the desired position, the expandable member is expanded to the second condition, causing the outer surface **4010** to engage the spinous processes S.

In some embodiments, the adjacent spinous processes can be distracted by a first expandable member (not shown) configured to distract bone. Upon distraction, the first expandable member is contracted and removed from the body. The medical device **4000** is then inserted percutaneously, advanced between the spinous processes S, placed in the desired position and expanded, as described above.

In some embodiments, the medical device **4000** is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, the overall sizes of portions of the medical device **4000** are increased by transitioning the expandable member **4002** from the first configuration to the second configuration after the medical device **4000** is inserted between the adjacent spinous processes S. When in the expanded second configuration, the sizes of portions of the medical device **4000** are greater than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the medical device **4000** in the expanded second configuration is between 3 and 25 millimeters across the opening.

FIGS. **62**A-**62**F are posterior views of a spinal implant **4100** according to an embodiment of the invention inserted between adjacent spinous processes S in a first lateral position (FIG. **62**C) and a second lateral position (FIG. **62**E). The spinal implant **4100** includes an expandable member **4102**, a sensor **4112** and a valve **4132**. The expandable member **4102** has an inner area (not shown), an outer surface **4110**, a support portion **4118**, a proximal retention portion **4114** and a distal retention portion **4116**. The expandable member **4102** is repeatably positionable in a first configuration (FIG. **62**B), a second configuration (FIGS. **62**C, **62**E and **62**F) and a third configuration (FIG. **62**D). When in each configuration, the expandable member **4102** has an associated volume, as will be discussed below.

In use, the spinal implant **4100** is positioned in the substantially contracted first configuration during insertion and/or removal (see FIG. **62**B). As discussed above, the spinal implant **4100** is inserted percutaneously between adjacent spinous processes S. The distal retention portion **4116** of the expandable member **4102** is inserted first and is moved past the spinous processes S until the support portion **4118** is positioned between the spinous processes S. When in the first configuration, the support portion **4118** can be can be sized to account for ligaments and tissue surrounding the spinous processes S. For purposes of clarity, such surrounding ligaments and tissue are not illustrated.

As illustrated in FIG. **62**C, once in position, the expandable member **4102** is expanded into the second configuration by conveying a fluid (not shown) from an area outside of the expandable member **4102** to the inner area of the expandable member **4102**. The fluid is conveyed by an expansion tool **4130**, such as a catheter, that is matingly coupled to the valve **4132**. The valve **4132** can be any valve suitable for sealably connecting the inner area of the expandable member **4102** to an area outside of the expandable member **4102**. For example, in some embodiments, the valve **4132** can be, for example a poppet valve, a pinch valve or a two-way check valve. In other embodiments, the valve includes a coupling portion (not shown) configured to allow the expansion tool **4130** to be repeatably coupled to and removed from the valve **4132**. For example, in some embodiments, the valve **4132** can include a threaded portion configured to matingly couple the expansion tool **4130** and the valve **4132**.

The fluid is configured to retain fluidic properties while resident in the inner area of the expandable member **4102**. In this manner, the spinal implant **4100** can be repeatably transitioned from the expanded second configuration to the first configuration and/or the third configuration by removing the fluid from the inner area of the expandable member **4102**. In some embodiments, the fluid can be a biocompatible liquid having constant or nearly constant properties. Such liquids can include, for example, saline solution. In other embodiments, the fluid can be a biocompatible liquid configured to have material properties that change over time while still retaining fluidic properties sufficient to allow removal of the fluid. For example, the viscosity of a fluid can be increased by adding a curing agent or the like. In this manner, the fluid can provide both the requisite structural support while retaining the ability to be removed from the inner area of the expandable member **4102** via the valve **4132**. In yet other embodiments, the fluid can be a biocompatible gas.

The outer surface **4110** of the support portion **4118** can distract the adjacent spinous processes S as the expandable member **4102** expands to the second configuration, as indicated by the arrows shown in FIG. **62**C. In some embodiments, the support portion **4118** does not distract the adjacent spinous processes S. For example, as discussed above, the adjacent spinous processes S can be distracted by a trocar and/or any other device suitable for distraction.

When in the second configuration, the outer surface **4110** of the support portion **4118** is configured to engage the spinous processes S for at least a portion of the range of motion of the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the engagement of the spinous processes S by the outer surface **4110** of the support portion **4118** is not continuous, but occurs upon spinal extension.

When in the second configuration, the proximal retention portion **4114** and the distal retention portion **4116** each have a size S**1** (shown in FIG. **63**) that is greater than the vertical distance D**1** (shown in FIG. **63**) between the spinous processes. In this manner, the proximal retention portion **4114** and the distal retention portion **4116** are disposed adjacent the sides of spinous processes S (i.e., either through direct contact or through surrounding tissue), thereby limiting movement of the spinal implant **4100** laterally along a longitudinal axis of the support portion **4118**.

The expandable member **4102** can be made from any number of biocompatible materials, such as, for example, PET, Nylons, cross-linked Polyethylene, Polyurethanes, and PVC. In some embodiments, the chosen material can be substantially inelastic, thereby forming a low-compliant expandable member **4102**. In other embodiments, the chosen material can have a higher elasticity, thereby forming a high-compliant expandable member **4102**. In yet other embodiments, the expandable member **4102** can be made from a combination of materials such that one portion of the expandable member **4102**, such as the support portion **4118**, can be low-compliant while other portions of the expandable member **4102**, such as the proximal retention portion **4114** and/or distal retention portion **4116** are more highly compliant. In yet other embodiments, a portion of the expandable member **4102** can include a rigid, inflexible material to provide structural stiffness. For example, the support portion **4118** can be constructed of a composite material that includes a rigid, inflexible material to facilitate distraction of the adjacent spinous processes.

In some embodiments, the expandable member **4102** includes a radiopaque material, such as bismuth, to facilitate tracking the position of the spinal implant **4100** during insertion and/or repositioning. In other embodiments, the fluid used to expand the expandable member **4102** includes a radiopaque tracer to facilitate tracking the position of the spinal implant **4100**.

In the illustrated embodiment, the spinal implant **4100** includes a sensor **4112** coupled to the expandable member **4102**. In some embodiments, the sensor **4112** is a strain gauge sensor that measures a force applied to the support portion **4118** of the expandable member **4102**. The sensor **4112** can include multiple strain gauges to facilitate measuring multiple force quantities, such as a compressive force and/or a tensile force. In other embodiments, the sensor **4112** is a variable capacitance type pressure sensor configured to measure a force and/or a pressure of the fluid contained within the inner portion of the expandable member **4102**. In yet other embodiments, the sensor **4112** is a piezoelectric sensor that measures a pressure of the fluid contained within the inner portion of the expandable member **4102**. In still other embodiments, the spinal implant **4100** can include multiple sensors **4112** located at various locations to provide a spatial profile of the force and/or pressure applied to the expandable member **4102**. In this manner, a practitioner can detect changes in the patient's condition, such those that may result in a loosening of the spinal implant **4100**.

In some embodiments, the sensor **4112** can be remotely controlled by an external induction device. For example, an external radio frequency (RF) transmitter (not shown) can be used to supply power to and communicate with the sensor **4112**. In other embodiments, an external acoustic signal transmitter (not shown) can be used to supply power to and communicate with the sensor **4112**. In such an arrangement, for example, the sensor can include a pressure sensor, of the types described above, for measuring a pressure; an acoustic transducers, and an energy storage device. The acoustic transducer converts energy between electrical energy and acoustic energy. The energy storage device stores the electrical energy converted by the acoustic transducer and supplies the electrical energy to support the operation of the pressure sensor. In this manner, acoustic energy from an external source can be received and converted into electrical energy used to power the pressure sensor. Similarly, an electrical signal output from the pressure sensor can be converted into acoustic energy and transmitted to an external source.

At times, the spinal implant **4100** may need to be repositioned. Such repositioning can be required, for example, to optimize the lateral position of the support portion **4118** during the insertion process. In other instances, the spinal implant **4100** can require repositioning subsequent to the insertion process to accommodate changes in the conditions of the patient. In yet other instances, the spinal implant **4100** can be removed from the patient. To allow for such repositioning and/or removal, the spinal implant is repeatably positionable in the first configuration, the second configuration and/or the third configuration. In FIG. **62**D, for example, the expandable member **4102** is contracted to the third configuration by removing all or a portion of the fluid contained in the inner area, as described above. In this manner, the spinal implant **4100** can be repositioned in a lateral direction, as indicated by the arrow. Once in the desired position, the expandable member is reexpanded to the second condition as described above. Finally, as shown in FIG. **62**F, the expansion tool **4130** is removed from the valve **4132**.

FIG. **63** is a lateral view of the spinal implant **4100** illustrated in FIGS. **62**A-**62**F inserted between adjacent spinous processes S in a second configuration. Although FIG. **63** only shows the proximal retention portion **4114** of the expandable member **4102**, it should be understood that the distal retention portion **4116** has characteristics and functionality similar to those described below for proximal retention portion **4114**. As illustrated, the proximal retention portion **4114** has a size S**1** that is greater than the vertical distance D**1** between the spinous processes S. In this manner, the proximal retention portion **4114** and the distal retention portion **4116** limit the lateral movement of the spinal implant **4100** when in the second configuration, as discussed above.

FIG. **64** is a lateral view of a spinal implant **4200** according to an embodiment of the invention inserted between adjacent spinous processes and in a second configuration. Similar to the spinal implant **4100** discussed above, the spinal implant **4200** includes an expandable member **4202** and a valve **4232**. The expandable member **4202** has a support portion (not shown), a proximal retention portion **4214** and a distal retention portion (not shown). The expandable member **4202** is repeatably positionable in a first configuration, a second configuration and/or a third configuration. When in each configuration, the expandable member **4202** has an associated volume, as discussed above.

In the illustrated embodiment, the proximal retention portion **4214** of the expandable member **4202** has a first radial extension **4236**, a second radial extension **4238** and a third radial extension **4240**. As illustrated, the distance S**1** between the ends of the radial extensions is greater than the vertical distance D**1** between the spinous processes S. In this manner, the proximal retention portion **4214** and the distal retention portion limit the lateral movement of the spinal implant **4200** when in the second configuration. In some embodiments, the proximal retention portion and the distal retention portion can assume a variety of different shapes.

FIGS. **65**A and **65**B are front views of a spinal implant **4300** according to an embodiment of the invention in a first configuration and a second configuration, respectively. The spinal implant **4300** includes a proximal expandable member **4304**, a distal expandable member **4306**, a support member **4308**, a sensor **4312** and a valve **4332**. The support member **4308** has an inner area (not shown) and an outer surface **4310**. The outer surface **4310** is configured to contact the spinous processes (not shown). In some embodiments, the support member **4308** distracts the adjacent spinous processes. In other embodiments, the support member **4308** does not distract the adjacent spinous processes. In yet other embodiments, the engagement of the spinous processes by the support member **4308** is not continuous, but occurs upon spinal extension.

The support member **4308** has a proximal portion **4324**, to which the proximal expandable member **4304** is coupled, and a distal portion **4326**, to which the distal expandable member **4306** is coupled. The proximal expandable member **4304** and the distal expandable member **4306** are each repeatably positionable in a first configuration (FIG. **65**A) and a second configuration (FIG. **65**B). As described above, the first configuration represents a substantially contracted condition in which the proximal expandable member **4304** and the distal expandable member **4306** each have a minimal volume. When the spinal implant **4300** is in the first configuration, it can be inserted, repositioned and/or removed. In the illustrated embodiment, the proximal expandable member **4304** and the distal expandable member **4306** are each contained within the inner area of the support member **4308** when the spinal implant **4300** is in the first configuration. In some embodiments, the proximal expandable member **4304** and the distal expandable member **4306** are not contained within the support member **4308**.

Conversely, the second configuration represents an expanded condition in which the proximal expandable member **4304** and the distal expandable member **4306** each have a large volume. When the spinal implant **4300** is in the second configuration, the proximal expandable member **4304** and the distal expandable member **4306** each have a size that is greater than the vertical distance between the spinous processes, as described above. In this manner, the proximal expandable member **4304** and the distal expandable member **4306** engage the spinous processes, thereby limiting the lateral movement of the spinal implant **4300**.

The proximal expandable member **4304** and the distal expandable member **4306** are expanded into the second configuration by conveying a fluid (not shown) from an area outside of each expandable member **4304**, **4306** to an inner area defined by each expandable member **4304**, **4306**. The fluid is conveyed through a valve **4332**, as described above. In the illustrated embodiment, the inner area of the proximal expandable member **4304**, the inner area of the distal expandable member **4306** and the inner area of the support member **4308** are in fluid communication with each other to form a single inner area. As such, the fluid can be conveyed to both the inner area of the proximal expandable member **4304** and the inner area of the distal expandable member **4306** by a single valve **4332**. In some embodiments, the inner areas of the proximal expandable member **4304** and the distal expandable member **4306** are not in fluid communication. In such an arrangement, each expandable member can be independently transformed between configurations.

The support member **4308** can be made from any number of biocompatible materials, such as, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, and the like. The material of the support member **4308** can have a tensile strength similar to or higher than that of bone. In some embodiments, the support member **4308** is substantially rigid. In other embodiments, the support member **4308** or portions thereof is elastically deformable, thereby allowing it to conform to the shape of the spinous processes. In yet other embodiments, the support member **4308** includes a radiopaque material, such as bismuth, to facilitate tracking the position of the spinal implant **4300** during insertion and/or repositioning.

The proximal expandable member **4304** and the distal expandable member **4306** can be made from any number of biocompatible materials, as discussed above. The proximal expandable member **4304** and the distal expandable member **4306** can be coupled to the support member by an suitable means, such as a biocompatible adhesive.

In the illustrated embodiment, the spinal implant **4300** includes a sensor **4312** coupled to the support member **4308**. As described above, the sensor **4312** can be configured to measure multiple force quantities and/or a pressure of the fluid contained within the proximal expandable member **4304** and the distal expandable member **4306**.

In another embodiment, the apparatus includes a support member, a proximal retention member, and a distal retention member. The support member is configured to be disposed between adjacent spinous processes. The proximal retention member has a first configuration in which the proximal retention member is substantially disposed within a proximal portion of the support member and a second configuration in which a portion of the proximal retention member is disposed outside of the support member. The distal retention member has a first configuration in which the distal retention member is substantially disposed within a distal portion of the support member and a second configuration in which a portion of the distal retention member is disposed outside of the support member.

In some embodiments, each of the proximal retention member and the distal retention member includes a first elongate member and a second elongate member. The second elongate member is configured to be slidably disposed within the first elongate member. The support member includes a side wall defining a multiple openings, each opening being configured to receive a portion of at least one of the first elongate member or the second elongate member therethrough.

In some embodiments, each of the proximal retention member and the distal retention member includes an elongate member having a longitudinal axis and a rotating member having a longitudinal axis normal to the longitudinal axis of the elongate member. A portion of the elongate member is flexible in a direction normal to its longitudinal axis. The rotating member is coupled to the elongate member and configured to rotate about its longitudinal axis, thereby moving the elongate member along its longitudinal axis.

In some embodiments, a method includes percutaneously inserting into a body a support member configured to be disposed between adjacent spinous processes. The support member defines an inner area and an opening substantially normal to the longitudinal axis that connects the inner area and an area outside the support member. The support member includes a retention member having a first configuration in which the retention member is substantially disposed within the inner area, and a second configuration in which a portion of the retention member is disposed through the opening to the area outside the support member. The support member is disposed to a location between the adjacent spinous processes when retention member is in the first configuration. The retention member is moved from the first configuration to the second configuration.

Although specific portions of the apparatus, such as one or more retention members, are configured to move between a first, a second configuration and/or a third configuration, for ease of reference, the entire apparatus may be referred to as being in a first configuration, a second configuration and/or a third configuration. However, one of ordinary skill in the art having the benefit of this disclosure would appreciate that the apparatus may be configured to include four or more configurations. Additionally, in some embodiments, the apparatus can be in many positions during the movement between the first, second and/or third configurations. For ease of reference, the apparatus is referred to as being in either a first configuration, a second configuration or a third configuration. Finally, in some embodiments, although an apparatus includes one or more retention members, the figures and accompanying description may show and describe only a single retention member. In such instances, it should be understood that the description of a single retention member applies to some or all other retention members that may be included in the embodiment.

FIGS. **66**A and **66**B are schematic illustrations of a posterior view of a medical device **3000** according to an embodiment of the invention disposed between two adjacent spinous processes S in a first configuration and a second configuration, respectively. The medical device **3000** includes a support member **3002**, a proximal retention member **3010** and a distal retention member **3012**. The support member **3002** has a proximal portion **3004** and a distal portion **3006**, and is configured to be disposed between the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the support member **3002** distracts the adjacent spinous processes S. In other embodiments, the support member **3002** does not distract the adjacent spinous processes S.

The proximal retention member **3010** has a first configuration in which it is substantially disposed within the proximal portion **3004** of the support member **3002**, as illustrated in FIG. **66**A. Similarly, the distal retention member **3012** has a first configuration in which it is substantially disposed within the distal portion **3006** of the support member **3002**. When the proximal retention member **3010** and the distal retention member **3012** are each in their respective first configuration, the medical device **3000** can be inserted between the adjacent spinous processes S.

The proximal retention member **3010** can be moved from the first configuration to a second configuration in which a portion of it is disposed outside of the support member **3002**, as illustrated in FIG. **66**B. Similarly, the distal retention member **3012** can be moved from the first configuration to a second configuration. When each is in their respective second configuration, the proximal retention member **3010** and the distal retention member **3012** limit lateral movement of the support member **3002** with respect to the spinous processes S by contacting the spinous processes S (i.e., either directly or through surrounding tissue). For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated.

In use, the adjacent spinous processes S can be distracted prior to inserting the medical device **3000** into the patient. When the spinous processes S are distracted, a trocar (not shown in FIG. **66**A or **66**B) can be used to define an access passageway (not shown in FIGS. **66**A and **66**B) for the medical device **3000**. In some embodiments, the trocar can be used to define the passage as well as to distract the spinous processes S.

Once an access passageway is defined, the medical device **3000** is inserted percutaneously and advanced, distal portion **3006** first, between the spinous processes S. The medical device **3000** can be inserted from the side of the spinous processes S (i.e., a posterior-lateral approach). The use of a curved shaft assists in the use of a lateral approach to the spinous processes S. Once the medical device **3000** is in place between the spinous processes S, the proximal retention member **3010** and the distal retention member **3012** are moved to their second configurations, either serially or simultaneously. In this manner, lateral movement of the support member **3002** with respect to the spinous processes S is limited.

When it is desirable to change the position of the medical device **3000**, the proximal retention member **3010** and the distal retention member **3012** are moved back to their first configurations, thereby allowing the support member **3002** to be moved laterally. Once the support member **3002** is repositioned, the medical device **3000** can be returned to the second configuration. Similarly, when it is desirable to remove the medical device **3000**, proximal retention member **3010** and the distal retention member **3012** are moved to their first configurations, thereby allowing the support member **3002** to be removed.

In some embodiments, the medical device **3000** is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, the overall sizes of portions of the medical device **3000** can be increased by moving the proximal retention member **3010** and the distal retention member **3012** to their respective second configurations after the medical device **3000** is inserted between the adjacent spinous processes S. When in the expanded second configuration, the sizes of portions of the medical device **3000** can be greater than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the medical device **3000** in the expanded second configuration is between 3 and 25 millimeters across the opening.

FIGS. **67**A, **67**B, **68**-**71** illustrate a spinal implant **3100** according to an embodiment of the invention. FIGS. **67**A and **67**B are perspective views of the spinal implant **3100** in a first configuration and a second configuration, respectively. The spinal implant **3100** includes a support member **3102**, a proximal retention member **3110** and a distal retention member **3112**. The support member **3102** is positioned between adjacent spinous processes S, as illustrated in FIGS. **68** and **69**. As shown in FIGS. **67**A and **67**B, the proximal retention member **3110** and the distal retention member **3112** are each repeatably positionable in a first configuration in which they are substantially disposed within the support member **3102** (FIG. **67**A), and a second configuration in which a portion of each retention member **3110**, **3112** is disposed outside of the support member **3102** (FIG. **67**B). When the spinal implant **3100** is in the first configuration, it can be inserted between the adjacent spinous processes S, repositioned between the adjacent spinous processes and/or removed from the patient. When the spinal implant **3100** is in the second configuration, its lateral movement is limited, thereby allowing the desired position of the support member **3102** to be maintained.

In some embodiments, the support member **3102** distracts the adjacent spinous processes S. In other embodiments, the support member **3102** does not distract the adjacent spinous processes S. In yet other embodiments, the engagement of the spinous processes S by the support member **3102** is not continuous, but occurs upon spinal extension.

The support member **3102** can be made from any number of biocompatible materials, such as, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, and the like. The material of the support member **3102** can have a tensile strength similar to or higher than that of bone. In some embodiments, the support member **3102** is substantially rigid. In other embodiments, the support member **3102** or portions thereof is elastically deformable, thereby allowing it to conform to the shape of the spinous processes. In yet other embodiments, the support member **3102** includes a radiopaque material, such as bismuth, to facilitate tracking the position of the spinal implant **3100** during insertion and/or repositioning.

In the illustrated embodiment, the spinal implant **3100** includes a sensor **3124** coupled to the support member **3102**. In some embodiments, the sensor **3124** is a strain gauge sensor that measures a force applied to the support member **3102**. In some embodiments, the sensor **3124** can include multiple strain gauges to facilitate measuring multiple force quantities, such as a compressive force and/or a bending moment. In other embodiments, the sensor **3124** is a variable capacitance type pressure sensor configured to measure a force and/or a pressure applied to the support member **3102**. In yet other embodiments, the sensor **3124** is a piezoelectric sensor that measures a force and/or a pressure applied to the support member **3102**. In still other embodiments, the spinal implant **3100** can include multiple sensors located at various locations to provide a spatial profile of the force and/or pressure applied to the support member **3102**. In this manner, a practitioner can detect changes in the patient's condition, such those that may result in a loosening of the spinal implant.

In some embodiments, the sensor **3124** can be remotely controlled by an external induction device. For example, an external radio frequency (RF) transmitter (not shown) can be used to supply power to and communicate with the sensor **3124**. In other embodiments, an external acoustic signal transmitter (not shown) can be used to supply power to and communicate with the sensor **3124**. In such an arrangement, for example, the sensor can include a pressure sensor, of the types described above, for measuring a pressure; an acoustic transducers, and an energy storage device. The acoustic transducer converts energy between electrical energy and acoustic energy. The energy storage device stores the electrical energy converted by the acoustic transducer and supplies the electrical energy to support the operation of the pressure sensor. In this manner, acoustic energy from an external source can be received and converted into electrical energy used to power the pressure sensor. Similarly, an electrical signal output from the pressure sensor can be converted into acoustic energy and transmitted to an external source.

The support member **3102** includes a sidewall **3108** that defines an inner area **3120** and multiple openings **3114** that connect the inner area **3120** to an area outside of the support member **3102**. When the spinal implant **3100** is in the first configuration, the proximal retention member **3110** and the distal retention member **3112** are substantially disposed within the inner area **3120** of the support member **3102**, as shown in FIG. **67**A. When the spinal implant **3100** is in the second configuration, a portion of each of the proximal retention member **3110** and the distal retention member **3112** extends through the openings **3114** to an area outside of the support member **3102**. In the second configuration, the proximal retention member **3110** and the distal retention member **3112** engage the adjacent spinous processes, thereby limiting lateral movement of the spinal implant **3100**.

The proximal retention member **3110** includes a first elongate member **3130** and a second elongate member **3132**. Similarly, the distal retention member **3112** includes a first elongate member **3131** and a second elongate member **3133**. As illustrated in FIG. **71**, which shows is a cross-sectional plan view of the proximal portion **3104** of the support member **3102**, the first elongate member **3130** is slidably disposed within a pocket **3134** defined by the second elongate member **3132**. A biasing member **3136**, such as a spring or an elastic member, is disposed within the pocket **3134** and is coupled to the first elongate member **3130** and the second elongate member **3132**. In this manner, the retention members can be biased in the second configuration. In other embodiments, the biasing member **3136** can be configured to bias the retention members in the first configuration. In yet other embodiments, the retention members do not include a biasing member, but instead use other mechanisms to retain a desired configuration. Such mechanisms can include, for example, mating tabs and slots configured to lockably engage when the retention members are in a desired configuration.

In use, the spinal implant **3100** is positioned in the first configuration during insertion, removal or repositioning. As discussed above, the spinal implant **3100** is inserted percutaneously between adjacent spinous processes. The distal portion **3106** of the support member **3102** is inserted first and is moved past the spinous processes until the support member **3102** is positioned between the spinous processes. The support member **3102** can be sized to account for ligaments and tissue surrounding the spinous processes S. In some embodiments, the support member **3102** contacts the spinous processes between which it is positioned during a portion of the range of motion of the spinous processes S. In some embodiments, the support member **3102** of spinal implant **3100** is a fixed size and is not compressible or expandable. In yet other embodiments, the support member **3102** can compress to conform to the shape of the spinous processes S. Similarly, in some embodiments, the proximal retention member **3110** and the distal retention member **3112** are substantially rigid. In other embodiments, the retention members or portions thereof are elastically deformable, thereby allowing them to conform to the shape of the spinous processes.

In the illustrated embodiment, the spinal implant **3100** is held in the first configuration by an insertion tool (not shown) that overcomes the force exerted by the biasing member **3136**, thereby disposing a portion of the first elongate member **3130** within the pocket **3134** of the second elongate member **3132**. In this manner, the spinal implant **3100** can be repeatedly moved from the first configuration to the second configuration, thereby allowing it to be repositioned and/or removed percutaneously. As illustrated in FIG. **70**, the first elongate member **3130** and the second elongate member **3132** each include notches **3138** configured to receive a portion of the insertion tool. When the insertion tool is released, the biasing member **3136** is free to extend, thereby displacing a portion of the first elongate member **3130** out of the pocket **3134** of the second elongate member **3132**. In this manner, portions of both the first elongate member **3130** and the second elongate member **3132** are extended through the adjacent openings **3114** and to an area outside of the support member **3102**. In some embodiments, the proximal retention member **3110** and the distal retention member **3112** are transitioned between their respective first and second configurations simultaneously. In other embodiments, the proximal retention member **3110** and the distal retention member **3112** are transitioned between their first and second configurations serially.

As illustrated, the first elongate member **3130** and the second elongate member **3132** each include one or more tabs **3140** that engage the side wall **3108** of the support member **3102** when in the second configuration, thereby ensuring that the first and second elongate members remain coupled to each other and that portions of the first and second elongate members remain suitably disposed within the support member **3102**. In other embodiments, the first elongate member **3130** and the second elongate member **3132** are coupled to each other by other suitable mechanisms, such as mating tabs and slots configured to engage when the retention member reaches a predetermined limit of extension.

FIGS. **72**, **73**A and **73**B are cross-sectional views of a spinal implant **3200** according to an embodiment of the invention. FIG. **72** illustrates a cross-sectional front view of the spinal implant **3200** in a second configuration, while FIGS. **73**A and **73**B illustrate a cross-sectional plan view of the spinal implant **3200** in the second configuration and a first configuration, respectively. The illustrated spinal implant **3200** includes a support member **3202**, a retention member **3210** and a rotating member **3250**. Although shown and described as including only a single retention member **3210**, some embodiments can include one or more additional retention members having characteristics and functionality similar to those described for the retention member **3210**.

As shown in FIGS. **73**A and **73**B, the retention member **3210** is repeatably positionable in a first configuration in which it is substantially disposed within the support member **3202**, and a second configuration in which a portion the retention member **3210** is disposed outside of the support member **3102**. When the spinal implant **3200** is in the first configuration, it can be inserted between adjacent spinous processes, repositioned between adjacent spinous processes and/or removed from the patient. When the spinal implant **3200** is in the second configuration, its lateral movement is limited, thereby allowing the desired position of the support member **3202** to be maintained.

The support member **3202** includes a sidewall **3208** that defines an inner area **3220** and multiple openings **3214** that connect the inner area **3220** to an area outside of the support member **3202**. When the spinal implant **3200** is in the first configuration, the retention member **3210** is substantially disposed within the inner area **3220** of the support member **3202**, as shown in FIG. **73**B. When the spinal implant **3200** is in the second configuration, a portion of the proximal retention member **3210** extends through the openings **3214** to an area outside of the support member **3202**. In the second configuration, the retention member **3210** is disposed adjacent the spinous processes, thereby limiting lateral movement of the spinal implant **3200**.

The retention member **3210** includes an elongate member **3228** having two end portions **3244**, a central portion **3242**, and a longitudinal axis L**1** (shown in FIG. **72**). A portion of the elongate member **3228** is flexible such that it can be wound along the rotating member **3250**, as described below. In some embodiments, the elongate member **3228** is monolithically formed such that it is flexible enough to be wound along the rotating member **3250** yet rigid enough to limit lateral movement of the support member **3202** when positioned in the second configuration. In other embodiments, the elongate member **3228** includes separate components that are coupled together to form the elongate member **3228**. For example, the central portion **3242** of the elongate member **3228** can be a distinct component having a greater amount of flexibility, while the end portions **3244** can be distinct components having a greater amount of rigidity.

In the illustrated embodiment, elongate member **3228** has one or more tabs **3240** that engage the side wall **3208** of the support member **3202** when in the second configuration, thereby ensuring that the elongate member **3228** does not freely extend entirely outside of the support member **3202**. In other embodiments, a portion of the elongate member **3228** is retained within the support member **3202** by other suitable mechanisms. For example, the width of the central portion **3242** of the elongate member **3228** can be greater than the width of the openings **3214**, thereby ensuring that a portion of the elongate member **3228** will remain within the support member **3202**.

The rotating member **3250** defines an outer surface **3252** and a slot **3254** through which the elongate member **3228** is disposed. The rotating member **3250** has a longitudinal axis L**2** (shown in FIG. **72**) about which it rotates. As illustrated in FIG. **73**B, as the rotating member **3250** rotates, the elongate member **3228** is wound along the outer surface **3252** of the rotating member **3250**. This causes the elongate member **3228** to move along its longitudinal axis L**1**, thereby causing the end portions **3244** of the elongate member **3228** to be retracted inwardly through the openings **3214**. In this manner, the retention member **3210** can be repeatedly transitioned between the first configuration and the second configuration.

In some embodiments, the rotating member **3250** is rotated using an insertion tool (not shown) that includes a ratchet mechanism. The insertion tool can rotate the rotating member **3250** in a number of different ways, such as, for example, manually, pneumatically or electronically.

FIGS. **74** and **75**A-**75**C are cross-sectional views of a spinal implant **3300** according to an embodiment of the invention. FIG. **74** illustrates a cross-sectional front view of the spinal implant **3300** in a second configuration, while FIGS. **75**A-**75**C illustrate a cross-sectional plan view of the spinal implant **3300** in the second configuration, a first configuration, and a third configuration, respectively. The illustrated spinal implant **3300** includes a support member **3302** and a retention member **3310**. Although shown and described as including only a single retention member **3310**, some embodiments can include one or more additional retention members having characteristics and functionality similar to those described for the retention member **3310**.

As shown in FIGS. **75**A-**75**C, the retention member **3310** is repeatably positionable in a first configuration, a second configuration and a third configuration. A portion the retention member **3310** is disposed outside of the support member **3302** when positioned in the second configuration. The retention member **3310** is substantially disposed within the support member **3202** when positioned in each of the first and third configurations. As illustrated in FIGS. **75**B and **75**C, the orientation of the retention member **3310** differs between the first and third configurations. In this manner, the position of the spinal implant **3300** can be positioned appropriately depending on the direction in which it is being moved. For example, the spinal implant **3300** may be positioned in the first configuration to facilitate lateral movement of the support member **3302** in a distal direction, such as during insertion. Conversely, the spinal implant **3300** may be positioned in the third configuration to facilitate lateral movement of the support member **3302** in a proximal direction, such as during removal.

The support member **3302** includes a sidewall **3308** that defines an inner area **3320** and multiple openings **3314** that connect the inner area **3320** to an area outside of the support member **3302**. When the spinal implant **3300** is in the second configuration, a portion of the proximal retention member **3310** extends through the openings **3314** to an area outside of the support member **3302**.

The retention member **3310** includes a first elongate member **3330**, a second elongate member **3332**, and a hinge **3360** having a longitudinal axis L**2** (shown in FIG. **74**). Each of the first elongate member **3330** and the second elongate member **3332** has a distal end portion **3344** that extends through the openings **3314** when the spinal implant **3300** is in the second configuration and a proximal end portion **3346** that is pivotally coupled to the hinge **3360**. In use, the hinge **3360** moves in a direction normal to its longitudinal axis L**2**, as indicated by the arrows in FIGS. **75**B and **75**C. The motion of the hinge is guided by a slot **3362** defined by the side wall **3308** of the support member **3302**. The movement of the hinge **3360** allows the each of the first elongate member **3330** and the second elongate member **3332** to rotate about the longitudinal axis L**2** of the hinge **3360**, thereby positioning the distal end portion **3344** of each elongate member substantially within the inner area **3320** of the support member **3302**.

In some embodiments, the slot **3362** includes detents or any other suitable mechanism (not shown) to maintain the hinge **3360** in the desired position. In other embodiments the hinge **3360** includes a biasing member (not shown) configured to bias the hinge **3360** in one of the first, second, or third configurations. In yet other embodiments, the elongate members include other suitable mechanisms to retain the retention member in a desired configuration. Such mechanisms can include, for example, mating tabs and slots configured to lockably engage when the elongate members are in a desired configuration.

In some embodiments, the first elongate member **3330** and the second elongate member **3332** are monolithically formed of a substantially rigid material. In other embodiments, the first elongate member **3330** and the second elongate member **3332** include separate components having different material properties. For example, the distal end portion **3344** can be formed from a material having a greater amount of flexibility, while the proximal end portion **3346** can be formed from a substantially rigid material. In this manner, movement of the spinal implant **3300** is not restricted when a portion of the of the distal end portion **3344** protrudes from the openings **3314** in either the first configuration or the third configuration.

FIGS. **76**A and **76**B are cross-sectional front views of a spinal implant **3400** according to an embodiment of the invention. The illustrated spinal implant **3400** includes a support member **3402**, a retention member **3410** and a rotating member **3450**. As shown in FIGS. **76**A and **76**B, the retention member **3410** is repeatably positionable in a first configuration in which it is substantially disposed within the support member **3402**, and a second configuration in which a portion the retention member **3410** is disposed outside of the support member **3402**. Although shown and described as including only a single retention member **3410**, some embodiments include one or more additional retention members having characteristics and functionality similar to those described for the retention member **3410**.

The support member **3402** includes a sidewall **3408** that defines an inner area **3420** and multiple openings **3414** that connect the inner area **3420** to an area outside of the support member **3402**. When the spinal implant **3400** is in the second configuration, a portion of the proximal retention member **3410** extends through the openings **3414** to an area outside of the support member **3402**.

The retention member **3410** includes a first elongate member **3430** and a second elongate member **3432**, each having a distal end portion **3444** that extends through the openings **3414** when the spinal implant **3400** is in the second configuration, a proximal end portion **3446**, and a longitudinal axis L**1**. As illustrated, the proximal end portions **3346** are coupled by two elastic members **3468**, such as a spring or an elastic band. In some embodiments, the proximal end portions **3346** are coupled by a single elastic member. In other embodiments, the proximal end portions **3346** are indirectly coupled via the rotating member **3450**. In such an arrangement, for example, a biasing member can be placed between the sidewall of the support member and each elongate member, thereby biasing each elongate member against the rotating member.

In the illustrated embodiment, the elongate members each include one or more tabs **3440** that engage the side wall **3408** of the support member **3402** when in the second configuration, thereby ensuring that the elongate members **3430**, **3432** does not freely extend entirely outside of the support member **3402**. In other embodiments, the elongate members do not include tabs, but are retained within the support member **3402** solely by the elastic members **3468**. In yet other embodiments, the width of a portion of the elongate members can be greater than the width of the openings **3414**, thereby ensuring that the elongate members will remain within the support member **3402**.

The rotating member **3450** defines an outer surface **3452** having an eccentric shape and includes a longitudinal axis (not shown) about which it rotates. As illustrated in FIGS. **76**A and **76**B, as the rotating member **3450** rotates about its longitudinal axis, a portion of the proximal end portion **3346** of the first elongate member **3430** and the second elongate member **3432** engage the outer surface **3452** of the rotating member **3250**. This causes the first elongate member **3430** and the second elongate member **3432** to move along their respective longitudinal axes L**1**, thereby causing the end portions **3444** of each elongate member to be extended outwardly through the openings **3414**, as indicated by the arrows in FIG. **76**A. In this manner, the retention member **3410** can be repeatedly transitioned between the first configuration and the second configuration.

In some embodiments, the rotating member **3450** is rotated using an insertion tool (not shown) that includes a ratchet mechanism. The insertion tool can rotate the rotating member **3450** in a number of different ways, such as, for example, manually, pneumatically or electronically.

FIGS. **77** and **78** illustrate a spinal implant **3500** according to an embodiment of the invention. FIG. **77** is a cross-sectional front view of the spinal implant **3500** in a second configuration. FIG. **78** is a cross-sectional plan view of the spinal implant **3500** taken along section A-A. The spinal implant **3500** includes a support member **3502** and a retention member **3510**. Although only shown as being in a second or expanded configuration, it is understood from the previous descriptions that the retention member **3510** is repeatably positionable in a first configuration in which it is substantially disposed within the support member **3502**, and the second configuration in which a portion the retention member **3510** is disposed outside of the support member **3502**.

As illustrated, the retention member **3510** includes a first elongate member **3530** and a second elongate member **3532**. The first elongate member **3530** is slidably disposed within a pocket **3534** defined by the second elongate member **3532**. The first elongate member **3530** and the second elongate member **3532** each include one or more tabs **3540** that are coupled to the side wall **3508** of the support member **3502** by one or more biasing members **3536**. In this manner, the retention member **3510** is biased in the first or retracted configuration. In other embodiments, the biasing members **3536** can be configured to bias the retention member **3510** in the second configuration. In yet other embodiments, the retention member **3510** is not retained by a biasing member **3536**, but rather uses other suitable mechanisms to retain the desired configuration.

In use, the retention member **3510** is transitioned from the first configuration to the second configuration by supplying a pressurized fluid (not shown) to the pocket **3534** via valve **3570**. The pressure exerted by the fluid on each of the first elongate member **3530** and the second elongate member **3532** overcomes the force exerted by the biasing members **3536**, thereby causing a portion the first elongate member **3530** to extend outwardly from the pocket **3534** of the second elongate member **3132**, thereby allowing a portion of each elongate member to extend through the adjacent openings **3514** and to an area outside of the support member **3502**. Similarly, the retention member **3510** is transitioned from the second configuration to the first configuration by opening the valve **3570** and relieving the pressure within the pocket **3534**. In this manner, the spinal implant **3500** can be repeatedly moved from the first configuration to the second configuration, thereby allowing it to be repositioned and/or removed percutaneously.

FIGS. **79**A and **79**B illustrate perspective views of a spinal implant **3600** according to an embodiment of the invention. The spinal implant **3600** includes a support member **3602**, a proximal retention member **3610**, a distal retention member **3612**, and an elastic member **3668**. The support member **3602** defines a longitudinal axis L**1** and has a sidewall **3608** that defines an inner area **3620** and has an outer surface **3616**. As illustrated in FIG. **79**B, the outer surface **3616** defines an area A normal to the longitudinal axis L**1**. As shown, the proximal retention member **3610** and the distal retention member **3612** are each repeatably positionable in a first configuration in which they are substantially disposed within the area A (FIG. **79**B), and a second configuration in which a portion of each retention member **3610**, **3612** is disposed outside of the area A (FIG. **79**A).

As illustrated, the proximal retention member **3610** and the distal retention member **3612** are coupled by the elastic member **3668**, a portion of which is disposed within the inner area **3620** of the support member **3602**. In the illustrated embodiment, the elastic member **3668** has a sidewall **3674** that defines a lumen **3676**. In other embodiments, the elastic member can be, for example, a spring, an elastic band, or any other suitable device for elastically coupling the proximal retention member **3610** and the distal retention member **3612**.

The proximal retention member **3610** includes a first elongate member **3630** and a second elongate member **3632**, each of which are pivotally coupled to a connection member **3678** by a hinge **3660**. Similarly, the distal retention member **3612** includes a first elongate member **3631** and a second elongate member **3633** each of which are pivotally coupled to a connection member **3678** by a hinge **3660**.

As illustrated in FIG. **79**A, when the spinal implant **3600** is in the second configuration, the elastic member **3668** exerts a biasing force on each connection member **3678**, thereby causing the connection members **3678** to remain adjacent to the support member **3602**. In this configuration, the first elongate member **3630** and the second elongate member **3632** are fully extended. The spinal implant **3600** is transitioned from the second configuration to the first configuration by stretching the elastic member **3668**, which allows the connection members **3678** to be disposed apart from the support member **3602**, thereby allowing the elongate members to move within the area A, as illustrated in FIG. **79**B. The support member **3602** includes slots **3672** in which the end portion of each elongate member can be disposed to maintain the spinal implant **3600** in the first configuration.

The elastic member **3668** can be stretched by an insertion tool (not shown), a portion of which can be configured to be disposed within the lumen **3676** of the elastic member **3668**. For example, a first portion of an insertion tool can engage the connection member **3678** of the proximal retention member **3610** while a second portion of the insertion tool can engage the connection member **3678** of the distal retention member **3612**. The tool can then be configured to exert an outward force on each of the connection members **3678**, thereby stretching the elastic member **3668** and allowing the spinal implant to transition from the second configuration to the first configuration.

While the spinal implants are shown and described above as having one or more retention members that extend substantially symmetrically from a support member when in a second configuration, in some embodiments, a spinal implant includes a retention member that extends asymmetrically from a support member when in a second configuration. For example, FIGS. **80-82** illustrate a spinal implant **3700** according to an embodiment of the invention that includes a proximal retention member **3710** and a distal retention member **3712** that extend asymmetrically from a support member **3702**. As shown in FIGS. **80** and **81**, the proximal retention member **3710** and the distal retention member **3712** are each repeatably positionable in a first configuration in which they are substantially disposed within the support member **3702**, and a second configuration in which a portion each is disposed outside of the support member **3702**.

The support member **3702** includes a sidewall **3708** that defines an inner area **3720** and two openings **3714** that connect the inner area **3720** to an area outside of the support member **3702**. When the spinal implant **3700** is in the second configuration, a portion of the proximal retention member **3710** and a portion of the distal retention member **3712** extend through the openings **3714** to an area outside of the support member **3702**.

In the illustrated embodiment, the proximal retention member **3710** and the distal retention member **3712** each include a first end portion **3746** and a second end portion **3744**. The first end portions **3746** of the proximal retention member **3710** and the distal retention member **3712** are coupled by a connecting member **3782** that has a longitudinal axis L**1** (shown in FIG. **77**). In some embodiments, the connecting member **3782**, the proximal retention member **3710** and the distal retention member **3712** are separate components that are coupled together to form the illustrated structure. In other embodiments, the connecting member **3782**, the proximal retention member **3710** and the distal retention member **3712** are monolithically formed.

The connecting member **3782** defines a longitudinal axis L**1**, about which it rotates. As illustrated, as the connecting member **3782** rotates, the proximal retention member **3710** and the distal retention member **3712** also rotate, thereby causing the end portions **3744** of the proximal retention member **3710** and the distal retention member **3712** to extend outwardly through the openings **3714**. In this manner, the retention member **3210** can be repeatedly transitioned between the first configuration and the second configuration.

In some embodiments, the connecting member **3782** is rotated using an insertion tool (not shown) that includes a ratchet mechanism. The insertion tool can rotate the connecting member **3782** in a number of different ways, such as, for example, manually, pneumatically or electronically.

In one embodiment, an apparatus includes a first body coupled to a second body. The first body and the second body collectively are configured to be releasably coupled to an implant device configured to be disposed between adjacent spinous processes. A first engaging portion is coupled to the first body, and a second engaging portion is coupled to the second body. The first engaging portion and/or the second engaging portion is configured to be received within a first opening defined by the implant device. The first body configured to be moved relative to the second body such that a distance between the first engaging portion and the second engaging portion is moved between a first distance and a second distance, and simultaneously a length of the implant device is moved between a first length and a second length.

In another embodiment, a kit includes an implant that is reconfigurable between an expanded configuration and a collapsed configuration while disposed between adjacent spinous processes. The implant has a longitudinal axis and defines an opening. A deployment tool is configured to be releasably coupled to the implant. The deployment tool includes an engaging portion configured to be removably received within the opening of the implant and extend in a transverse direction relative to the longitudinal axis when the deployment tool is coupled to the implant. The deployment tool is configured to move the implant between the collapsed configuration and the expanded configuration while the implant is disposed between the adjacent spinous processes.

FIGS. **83** and **84** are schematic illustrations of a medical device according to an embodiment of the invention positioned between two adjacent spinous processes. FIG. **83** illustrates the medical device in a first configuration, and FIG. **84** illustrates the medical device in a second configuration. The medical device **6000** includes an implant **6010** and a deployment tool **6020**. The implant **6010** includes a distal portion **6012**, a proximal portion **6014**, and a central portion **6016**. The implant **6010** is configured to be inserted between adjacent spinous processes S. The central portion **6016** is configured to contact and provide a minimum spacing between the spinous processes S when adjacent spinous processes S move toward each other during their range of motion to prevent over-extension/compression of the spinous processes S. In some embodiments, the central portion **6016** does not substantially distract the adjacent spinous processes S. In other embodiments, the central portion **6016** does distract the adjacent spinous processes S. The implant **6010** and the deployment tool **6020** can each be inserted into a patient's back and moved in between adjacent spinous processes from the side of the spinous processes (i.e., a posterior-lateral approach). The use of a curved insertion shaft assists in the use of a lateral approach to the spinous processes S.

The implant **6010** has a collapsed configuration in which the proximal portion **6014**, the distal portion **6012** and the central portion **6016** share a common longitudinal axis. In some embodiments, the proximal portion **6014**, the distal portion **6012** and the central portion **6016** define a tube having a constant inner diameter. In other embodiments, the proximal portion **6014**, the distal portion **6012** and the central portion **6016** define a tube having a constant outer diameter and/or inner diameter. In yet other embodiments, the proximal portion **6014**, the distal portion **6012** and/or the central portion **6016** have different inner diameters and/or outer diameters.

The implant **6010** can be moved from the collapsed configuration to an expanded configuration, as illustrated in FIG. **84**. In the expanded configuration, the proximal portion **6014** and the distal portion **6012** each have a larger outer perimeter (e.g., outer diameter) than when in the collapsed configuration, and the proximal portion **6014** and the distal portion **6012** each have a larger outer perimeter (e.g., outer diameter) than the central portion **6016**. In the expanded configuration, the proximal portion **6014** and the distal portion **6012** are positioned to limit lateral movement of the implant **6010** with respect to the spinous processes S. The proximal portion **6014** and the distal portion **6012** are configured to engage the spinous process (i.e., either directly or through surrounding tissue and depending upon the relative position of the adjacent spinous processes S) in the expanded configuration. For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated.

In some embodiments, the proximal portion **6014**, the distal portion **6012** and the central portion **6016** are monolithically formed. In other embodiments, one or more of the proximal portion **6014**, the distal portion **6012** and/or the central portion **6016** are separate components that can be coupled together to form the implant **6010**. For example, the proximal portion **6014** and distal portion **6012** can be monolithically formed and the central portion **6016** can be a separate component that is coupled thereto. These various portions can be coupled, for example, by a friction fit, welding, adhesive, etc.

The implant **6010** is configured to be coupled to the deployment tool **6020**. The deployment tool **6020** includes an elongate member **6022** and two or more engaging portions **6024**. In the embodiment shown in FIGS. **83** and **84**, there are two engaging portions **6024-1** and **6024-2** shown, but it should be understood that more than two engaging portions **6024** can be included. The elongate member **6022** can include a first body portion **6026** coupled to a second body portion **6028**. In some embodiments, the first body portion **6026** is threadedly coupled to the second body portion **6028**. The first body portion **6026** and the second body portion **6028** are configured to be moved relative to each other. For example, a threaded connection between the first body portion **6026** and the second body portion **6028** can be used to decrease or increase a distance between the first body portion **6026** and the second body portion **6028**. The first body portion **6026** and the second body portion **6028** can be a variety of different shapes and sizes, and can be the same shape and/or size, or have a different shape and/or size than each other. For example, in some embodiments, the first body portion includes a straight distal end and a straight proximal end, and the second body portion includes a straight proximal end and a curved or rounded distal end. The curved distal end can assist with the insertion of the deployment tool into a lumen of an implant and also with the insertion of the medical device into a portion of a patient's body.

The first engaging portion **6024-1** can be coupled to the first body portion **6026** and the second engaging portion **6024-2** can be coupled to the second body portion **6028**. The engaging portions **6024** can be, for example, substantially rectangular, square, circular, oval, semi-circular, or quarter-moon shaped. The engaging portions **6024**, can be spring-loaded devices coupled to the elongate member **6022** of the deployment tool **6020**, such that the engaging portions **6024** are biased into a position transverse to a longitudinal axis A defined by the elongate member **6022** and extending from an outer surface of the elongate member **6022**. Upon force exerted on the engaging portions **6024**, the engaging portions **6024** can be moved or collapsed to a position substantially below the outer surface of the elongate member **6022**. The engaging portions **6024** can alternatively be coupled to an actuator (not shown) configured to move the engaging portions **6024** from a position transverse to the longitudinal axis A and extending from an outer surface of the elongate member **6022**, to a position substantially below the outer surface of the elongate member **6022**.

FIGS. **94-96** illustrate the movement of an engaging portion **6024** as it passes by a spinous process S when an implant and deployment tool (collectively also referred to as medical device) are coupled together and being inserted between adjacent spinous processes. In some cases, as the medical device is being inserted, an engaging portion **6024** extending from a proximal portion of an implant may come into contact with a spinous process (or other tissue). To allow the engaging portion **6024** to pass by the spinous process, the engaging portion **6024** can be moved downward (as described above) so as to clear the spinous process. FIG. **94** illustrates an engaging portion **6024** having a spring-biased construction. The engaging portion **6024** includes a curved portion **6048** that initially contacts the spinous process S as the medical device is being inserted adjacent a spinous process S. As the curved portion **6048** contacts the spinous process S, the engaging portion **6024** is moved downward at least partially into an interior of the implant **6010**, as shown in FIG. **95**. The engaging portion **6024** moves back to an extended position (e.g., extending transversely from a surface of the implant **6010**) after the engaging portion clears the spinous process S, as shown in FIG. **96**, due to the bias of the spring (not shown).

The deployment tool **6020** can be used to move the implant **6010** from the collapsed configuration to the expanded configuration, and vice versa, as will be discussed in more detail below. The first body portion **6026** and the second body portion **6028** are collectively configured to be inserted at least partially into a lumen (not shown in FIGS. **83** and **84**) of the implant **6010**, such that at least one engaging portion **6024** extends through an opening (not shown in FIGS. **83** and **84**) defined by the implant **6010**. The implant **6010** can be configured with one or more such openings, each of which is configured to receive an engaging portion **6024** disposed on the elongate member **6022** (e.g., the first body portion **6026** or the second body portion **6028**). The openings defined by the implant **6010** can be, for example, the openings can be circular, oval, square, rectangular, etc. FIG. **85** illustrates an example of an implant **6110** defining curved rectangular openings **6136**, and FIG. **98** illustrates an implant **6310** defining curved round or circular openings **6336**.

The openings are at least partially defined by an edge (not shown in FIGS. **83** and **84**) on the implant **6010**. The engaging portions **6024** on the deployment tool **6020** include a surface (not shown in FIGS. **83** and **84**) that is configured to engage or contact the edge of the openings of the implant **6010** when the elongate member **6022** is inserted into the lumen of the implant **6010**.

In use, the spinous processes S can be distracted prior to inserting the implant **6010**. When the spinous processes are distracted, a trocar can be used to define an access passage for the implant **6010**. In some embodiments, the trocar can be used to define the passage as well as distract the spinous processes S. Once an access passage is defined, the implant **6010** can be inserted percutaneously and advanced between the spinous processes, distal end **6012** first, until the central portion **6016** is located between the spinous processes S. In some embodiments, the implant **6010** can be coupled to the deployment tool **6020** prior to being inserted between the adjacent spinous processes. In other embodiments, the implant **6010** can be inserted between adjacent spinous processes without being coupled to the deployment tool **6020**. In the latter configuration, after the implant **6010** is disposed between the adjacent spinous processes, the deployment tool **6020** can be inserted into the lumen defined by the implant **6010**.

Once the implant **6010** is in place between the spinous processes, and the deployment tool **6020** is in position within the lumen of the implant **6010**, the implant **6010** can be moved to the second configuration (i.e., the expanded configuration) by actuating the deployment tool **6020**. For example, when the deployment tool **6020** is inserted into the lumen of the implant **6010**, the first body portion **6026** is positioned at a first distance from the second body portion **6028**, and the first engaging portion **6024-1** is positioned at a first distance from the second engaging portion **6024-2**, as shown in FIG. **83**. The deployment tool **6020** can then be actuated at a proximal end portion (e.g., by turning a handle) (not shown in FIGS. **83** and **84**) causing the threaded coupling between the first body portion **6026** and the second body portion **6028** to move the first body portion **6026** and the second body portion **6028** towards each other such that the first body portion **6026** is now at a second distance (closer) from the second body portion **6028**, as shown in FIG. **84**. This movement likewise moves the first engaging portion **6024-1** and the second engaging portion **6024-2** to a closer position relative to each other. For example, in FIG. **83**, the first engaging portion **6024-1** is positioned at a distance from the second engaging portion **6024-2** that is greater than a distance between the first engaging portion **6024-1** and the second engaging portion **6024-2** shown in FIG. **84**.

As the engaging portions **6024-1** and **6024-2** are moved relative to each other, the surface (described above and described in more detail below) on the engaging portions **6024** imparts a force on the edge (described above and described in more detail below) of the opening defined by the implant causing the implant to move from the collapsed configuration to the expanded configuration.

The deployment tool **6020** is configured such that the deployment tool **6020** can be removed from the implant **6010** after the implant has been moved to the expanded configuration. The implant can remain disposed between the spinous processes indefinitely or removed as needed. For example, the deployment tool **6020** can be reinserted into the lumen of the implant **6010** and actuated in an opposite direction to cause the implant **6010** to be moved from the expanded configuration back to the collapsed configuration. In the collapsed configuration, the implant can be removed from the patient's body or repositioned to a new location between the spinous processes.

In some embodiments, the implant **6010** is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, the sizes of portions of the implant are expanded after the implant is inserted between the spinous processes. Once expanded, the sizes of the expanded portions of the implant are greater than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the implant in the expanded configuration is between 3 and 25 millimeters across the opening.

FIGS. **85-87** illustrate an implant according to an embodiment of the invention. An implant **6110** includes a proximal portion **6114**, a distal portion **6112**, and a central portion **6116**. The implant **6110** also defines multiple openings **6132** on an outer surface of the implant **6110**. The openings **6132** are in communication with a lumen **6158** (shown in FIG. **92**) defined by the implant **6110**. The openings **6132** are partially defined by a first edge **6136** and a second edge **6138**. The implant **6110** includes expandable portions disposed at the distal portion **6112** and the proximal portion **6114**. The expandable portions **6140** can be coupled to the implant **6110** or formed integral with the implant **6110**, as shown in FIG. **97**. As shown in FIG. **97**, elongated slots **6134** can be defined on an outer surface of the implant **6110**. The elongated slots **6134** create weakened areas on the implant **6110** that allow the expandable portions **6140** to fold when exposed to axial force, forming extensions **6142**, as shown in FIG. **86**.

The implant **6110** can be inserted between adjacent spinous processes (not shown) in a collapsed configuration, as shown in FIG. **85**, and then moved to an expanded configuration, as shown in FIG. **86**. The implant **6110** can then be moved back to a collapsed configuration as shown in FIG. **87**, which illustrates the expandable portions **6140** in a partially collapsed configuration. Although FIG. **87** shows a partially collapsed configuration, in some embodiments, the implant can be moved back to the collapsed configuration as shown in FIG. **85**.

To move the implant **6110** from the collapsed configuration to the expanded configuration, and vice versa, a deployment tool, as described above and as shown in FIGS. **88-90**, can be used. The deployment tool **6120** includes an elongate member **6122** coupled to a handle **6144**. The elongate member **6122** includes a first body portion **6126** coupled to a second body portion **6128** through a threaded coupling **6150**. A pair of engaging portions **6124-1** are disposed on the first body portion **6126**, and a pair of engaging portions **6124-2** are disposed on the second body portion **6128**. The engaging portions **6124-1** and **6124-2** (also collectively referred to as engaging portions **6124**) include a surface **6146** and a rounded portion **6148**. The threaded coupling **6150** between the first body portion **6126** and the second body portion **6128** is used to move the first body portion **6126** and the second body portion **6128** such that a distance between the first body portion **6126** and the second body portion **6128** is changed. For example, FIG. **89** illustrates a first distance d-**1** between the first body portion **6126** and the second body portion **6128**, and FIG. **90** illustrates a second distance d-**2** between the first body portion **6126** and the second body portion **6128**. As shown in FIGS. **89** and **90**, as the distance between the first body portion **6126** and the second body portion **6128** is changed, a distance between the engaging portions **6124-2** and **6124-2** is also changed.

In use, the first body portion **6126** and the second body portion **6128** are collectively disposed within the lumen **6158** of the implant **6110**, such that the engaging portions **6124** extend through the openings **6132** and transverse to an axis B defined by the implant **6110**, as shown in FIGS. **91-93**. In this position, the surface **6146** of the engaging portions **6124** is configured to contact the edge **6136** of the openings **6132**. FIGS. **91** and **92** illustrate the first body portion **6126** and the second body portion **6128** disposed within the lumen of the implant **6110**, when the implant is in a collapsed configuration. In this position, the first body portion **6126** is at a first distance from the second body portion **6128**, the engaging portions **6124-1** are at a first distance from the engaging portions **6124-2**, and the implant has a first length L-**1**.

When the implant is positioned between spinous processes S, the deployment tool **6120** can be actuated to move the implant **6110** to the expanded configuration, as shown in FIG. **93**. When the deployment tool **6120** is actuated, the first body portion **6126** is moved closer to the second body portion **6128**, and the engaging portions **6124-1** are moved closer to the engaging portions **6124-2**. When this occurs, the surface **6146** on the engaging portions **6124** impart a force on the edge **6136** of the openings **6132**, which axially compresses the implant **6110** until the implant **6110** has a second length L-**2**, as shown in FIG. **93**.

To move the implant **6110** back to the collapsed configuration, the deployment tool **6120** can be reconfigured such that the surface **6146** of the engaging portions **6124** are positioned facing an opposite direction and configured to contact the edge **6138** of the implant **6110**, as shown in FIG. **102**. In some embodiments, the engaging portions **6124** can be, for example, removed and re-coupled to the elongate member **6122** (e.g., the first body portion **6126** and the second body portion **6128**) such that the same engaging portions **6124** are simply repositioned. In other embodiments, a second deployment tool can be used having engaging portions positioned in the opposite direction. In either case, the deployment tool is inserted into the lumen **6158** of the implant **6110** as done previously, such that the engaging portions **6124** extend through the openings **6132** of the implant **6110** and the surface **6146** contacts the edge **6136** of the implant **6110**. The deployment tool **6120** is then actuated in an opposite direction (e.g., turned in an opposite direction) such that the first body portion **6126** and the second body portion **6128** are threadedly moved further away from each other. In doing so, the engaging portions **6124-1** are moved further away from the engaging portions **6124-2**, and the surface **6146** of the engaging portions **6124** impart a force on the edge **6138** (instead of edge of **6136**) of openings **6132**, which moves the implant **6110** back to the collapsed or straightened configuration. Thus, the implant described in all of the embodiments of the invention can be repeatedly moved between the collapsed and expanded configurations as necessary to insert, reposition or remove the implant as desired.

FIG. **99** illustrates a deployment tool according to another embodiment of the invention. A deployment tool **6220** includes an elongate member **6222** having a first body portion **6226** coupled to a second body portion **6228** through a threaded coupling **6250**. In this embodiment, the deployment tool **6220** includes two sets of four (8 total) engaging portions **6224** (only six engaging portions are shown in FIG. **99**). A first set of engaging portions **6224-1** are coupled to the first body portion **6226**, and a second set of engaging portions **6224-2** are coupled to the second body portion **6228**. The engaging portions **6224** include a first surface **6246** and a second surface **6252**. When the deployment tool **6220** is coupled to an implant, the first surface **6246** is configured to contact an edge of an opening defined on the implant (such as edge **6136** on implant **6110**), and the second surface **6252** is configured to contact an opposite edge on the opening defined by the implant (such as edge **6138** on implant **6110**).

Thus, in this embodiment, the deployment tool **6220** can be inserted into an implant and used to move the implant between a collapsed configuration and an expanded configuration without having to reposition the engaging portions **6224**, or use a second deployment tool. To move the implant from a collapsed configuration to an expanded configuration, the deployment tool **6220** is actuated in a first direction. To move the implant back to the collapsed configuration, the deployment tool **6220** is actuated in an opposite direction (e.g., turned in an opposite direction). When the deployment tool **6220** is actuated to move the implant from the collapsed configuration to the expanded configuration, the surface **6246** of the engaging portions **6224** impart a force on an edge of an opening (e.g., edge **6136** on implant **6110**), causing the implant to be axially compressed, as previously described. When the deployment tool **6220** is actuated to move the implant from the expanded configuration to the collapsed configuration, the surface **6252** of the engaging portions **6224** imparts a force on an opposite edge of the opening (e.g., edge **6138** on implant **6110**), causing the implant to be substantially straightened as previously described.

FIG. **100** illustrates a deployment tool according to another embodiment of the invention. A deployment tool **6420** is similar to the deployment tool **6220** described above, except in this embodiment, there are only two sets of two engaging portions **6424** (4 total). The engaging portions **6424** are similar to the engaging portions **6224** except the engaging portions **6424** are substantially rectangular shaped. The engaging portions **6424** include a surface **6446** configured to contact an edge of an opening defined by an implant, and a surface **6452** configured to contact an opposite edge of the opening defined by the implant.

FIG. **101** illustrates a deployment tool according to yet another embodiment of the invention. A deployment tool **6520** is similarly constructed and functions similarly to the previous embodiments. The deployment tool **6520** includes an elongate member **6522** that includes a first body portion **6526** and a second body portion **6528**. In this embodiment, the first body portion **6526** and the second body portion **6528** are smaller than illustrated in the previous embodiments, and engaging portions **6524** are coupled to the first body portion **6526** and the second body portion **6528** that are more elongate than previously shown.

A kit according to an embodiment of the invention can include at least one implant and at least one deployment tool as described above. For example, a kit can include an implant and two deployment tools, one deployment tool configured to be used to move the implant from a collapsed configuration to an expanded configuration, and another deployment tool configured to be used to move the implant from the expanded configuration to the collapsed configuration. Alternatively, a kit can include a single deployment tool have multiple engaging portions as described herein, that can be releasably coupled to an elongate member of a deployment tool. For example, one type or style of engaging portion can be used to move the implant from a collapsed configuration to an expanded configuration, and another type or style of engaging portion can be used to move the implant from the expanded configuration to the collapsed configuration. The kit can include engaging portions having one of a variety of different shapes and sizes, such that a user can select a particular engaging portion(s) for use in a particular application.

FIGS. **118-120** illustrate an implant **6610** according to another embodiment of the invention. The implant **6610** can be moved between a collapsed configuration, as shown in FIGS. **118** and **119**, and an expanded configuration, as shown in FIGS. **120-122**. The implant **6610** includes an outer shell **6670** having a distal portion **6612**, a proximal portion **6614**, and a central portion **6616**. The outer shell **6670** defines a series of openings **6618** disposed between the distal portion **6612** and the central portion **6616**, and the proximal portion

6614 and the central portion 6616. The outer shell 6670 includes a series of tabs 6620, a pair of which are disposed opposite each other, along the longitudinal axis of the implant 6610, on either side of each opening 6618. The outer shell 6670 also includes expandable portions 6640, which form extensions 6642 that extend radially from the outer shell 6670 when the implant 6610 is in the expanded configuration. As illustrated best in FIGS. 120-122, the arrangement of the openings 6618 and the tabs 6620 effect the shape and/or size of the extensions 6642. In some embodiments, the opposing tabs 6620 can be configured to engage each other when the implant 6610 is in the expanded configuration, thereby serving as a positive stop to limit the amount of expansion. In other embodiments, for example, the opposing tabs 6620 can be configured to engage each other during the expansion process, thereby serving as a positive stop, but remain spaced apart when the implant 6610 is in the expanded configuration (see, for example, FIGS. 120-122). In such embodiments, the elastic properties of the extensions 6642 can cause a slight "spring back," thereby causing the opposing tabs 6620 to be slightly spaced apart when the expansion device (also referred to as an insertion tool or a deployment tool) is disengaged from the implant 6610.

As illustrated best in FIG. 118, when the implant is in the collapsed configuration, the expandable portions 6640 are contoured to extend slightly radially from remaining portions of the outer shell 6670. In this manner, the expandable portions 6640 are biased such that when a compressive force is applied, the expandable portions 6640 will extend outwardly from the outer shell 6670. The expandable portions 6640 can be biased using any suitable mechanism. In some embodiments, for example, the expandable portions can be biased by including a notch in one or more locations along the expandable portion, as previously described. In other embodiments, the expandable portions can be biased by varying the thickness of the expandable portions in an axial direction. In yet other embodiments, the expandable portions can be stressed or bent prior to insertion such that the expandable portions are predisposed to extend outwardly when a compressive force is applied to the implant. In such embodiments, the radius of the expandable portions is greater than that of the remaining portions of the implant (e.g., the remaining cylindrical portions of the implant).

The implant 6610 also includes an inner core 6672 disposed within a lumen 6658 defined by the outer shell 6670. The inner core 6672 is configured to maintain the shape of the implant 6610 during insertion, to prevent the expandable portions from extending inwardly into a region inside of the outer shell 6670 during deployment and/or to maintain the shape of the central portion 6616 once the implant is in its desired position. As such, the inner core 6670 can be constructed to provide increased compressive strength to the outer shell 6670. In other words, the inner core 6672 can provide additional structural support to outer shell 6670 (e.g., in a direction transverse to the axial direction) by filling at least a portion of the region inside outer shell 6670 (e.g., lumen 6658) and contacting the walls of outer shell 6670. This can increase the amount of compressive force that can be applied to the implant 6610 while the implant 6610 still maintains its shape and, for example, the desired spacing between adjacent spinous processes. In some embodiments, the inner core 6672 can define a lumen 6673, while in other embodiments, the inner core 6672 can have a substantially solid construction. As illustrated, the inner core 6672 is fixedly coupled to the outer shell 6670 with a coupling portion 6674, which is configured to be threadedly coupled to the distal portion 6612 of the outer shell 6670. The distal end of the coupling portion 6674 of the inner core 6672 includes an opening 6675 configured to receive a tool configured to deform the distal end of the coupling portion 6674. In this manner once the inner core 6672 is threadedly coupled to the outer shell 6670, the coupling portion 6674 can be deformed or peened to ensure that the inner core 6672 does not become inadvertently decoupled from the outer shell 6670. In some embodiments, an adhesive, such as a thread-locking compound can be applied to the threaded portion of the coupling portion 6674 to ensure the that the inner core 6672 does not inadvertently become decoupled from the outer shell 6670. Although illustrated as being threadedly coupled, the inner core 6672 can be coupled to the outer shell 6670 by any suitable means. In some embodiments, for example, the inner core 6672 can be coupled to the central portion 6616 of the outer shell 6670 by, for example, a friction fit. In other embodiments, the inner core 6672 can be coupled to the outer shell 6670 by an adhesive. The inner core 6672 can have a length such that the inner core 6672 is disposed within the lumen 6658 along substantially the entire length of the outer shell 6670 or only a portion of the length of the outer shell 6670.

The proximal portion of the inner core 6672 includes an opening 6673 configured to receive a portion of an expansion device 7500 (also referred to as an insertion tool or a deployment tool), as shown in FIGS. 125-132. The expansion device 7500 is similar to the expansion device 1500 shown and described above (see e.g. FIGS. 15-17). The expansion device 7500 differs, however, from expansion device 1500 in that the expansion device 7500 includes spacer 7532 configured to cooperate with the inner core 6672 of the implant 6610. In such an arrangement, the threaded portion of rod 7570 of the expansion device 7500 removably engages to the internal threads 6676 of the inner core 6672 of the implant 6610, rather than coupling directly to the distal portion of the implant (as shown in FIGS. 15A and 15B). Although the inner core 6672 is shown as being threadedly coupled to the expansion device 7500, the inner core 6672 can be removably coupled to the expansion device 7500 by any suitable means, such as a protrusion and detent arrangement.

In use, once the implant 6610 is positioned on the implant support portion 7530 of the expansion tool 7500 (see FIGS. 125 and 126), the implant is inserted into the patient's body and disposed between adjacent spinous processes. Once disposed between adjacent spinous processes, the expansion device can be used to move the inner core 6672 axially towards the proximal portion 6614 of the implant 6610 while simultaneously maintaining the position of the proximal portion 6614 of the implant 6610, as shown in FIGS. 130 and 132. In this manner, a compressive force is applied along the longitudinal axis of the outer shell 6670, thereby causing the outer shell 6670 to fold or bend to form extensions 6642 as described above. As illustrated, a portion of the spacer 7532 is received within the receiving area 7542 of the support portion 7530 as the implant 6610 is placed in the expanded configuration. Similarly, to move the implant 6610 from the expanded configuration to the collapsed configuration, the expansion device is actuated in the opposite direction to impart an axial force on the distal portion 6612 of the outer shell 6610 in a distal direction, moving the distal portion 6612 distally, and moving the implant 6610 to the collapsed configuration.

Once the implant 6610 is in its expanded configuration (see FIGS. 129-132), the implant 6610 can be disengaged from the expansion device 7500 by disengaging the distal portion of the rod 7570 from the opening 6673. The rod 7570 can be disengaged by actuating the knob assembly **7515** rotate the rod **7570** relative to the shaft **7520**, as discussed above.

Although shown and described above without reference to any specific dimensions, in some embodiments, the outer shell **6670** can have a cylindrical shape having a length of approximately 34.5 mm (1.36 inches) and a diameter between 8.1 and 14.0 mm (0.32 and 0.55 inches). In some embodiments, the wall thickness of the outer shell can be approximately 5.1 mm (0.2 inches).

Similarly, in some embodiments, the inner core **6672** can have a cylindrical shape having an overall length of approximately 27.2 mm (1.11 inches) and a diameter between 8.1 and 14.0 mm (0.32 and 0.55 inches).

In some embodiments, the shape and size of the openings **6618** located adjacent the distal portion **6612** can be the same as that for the openings **6618** located adjacent the proximal portion **6614**. In other embodiments, the openings **6618** can have different sizes and/or shapes. In some embodiments, the openings **6618** can have a length of approximately 11.4 mm (0.45 inches) and a width between 4.6 and 10 mm (0.18 and 0.40 inches).

Similarly, the shape and size of the tabs **6620** can be uniform or different as circumstances dictate. In some embodiments, for example, the longitudinal length of the tabs **6620** located adjacent the proximal portion **6614** can be shorter than the longitudinal length of the tabs **6620** located adjacent the distal portion **6612**. In this manner, as the implant is moved from the collapsed configuration to the expanded configuration, the tabs adjacent the distal portion will engage each other first, thereby limiting the expansion of the expandable portions **6640** adjacent the distal portion **6612** to a greater degree than the expandable portions **6642** located adjacent the proximal portion **6614**. In other embodiments, the longitudinal length of the tabs can be the same. In some embodiments, the longitudinal length of the tabs can be between 1.8 and 2.8 mm (0.07 and 0.11 inches). In some embodiments, the end portions of opposing tabs **6620** can have mating shapes, such as mating radii of curvature, such that the opposing tabs **6620** engage each other in a predefined manner.

Although illustrated as having a generally rectangular shape, the expandable portions **6640** and the resulting extensions **6642** can be of any suitable shape and size. In some embodiments, for example, the expandable portions can have a longitudinal length of approximately 11.4 mm (0.45 inches) and a width between 3.6 and 3.8 mm (0.14 and 0.15 inches). In other embodiments, size and/or shape of the expandable portions located adjacent the proximal portion **6614** can be different than the size and/or shape of the tabs **6620** located adjacent the distal portion **6612**. Moreover, as described above, the expandable portions **6640** can be contoured to extend slightly radially from the outer shell **6670**. In some embodiments, for example, the expandable portions can have a radius of curvature of approximately 12.7 mm (0.5 inches) along an axis normal to the longitudinal axis of the implant.

In some embodiments, the expandable portions **6640** and the outer shell **6670** are monolithically formed. In other embodiments, the expandable portions **6640** and the outer shell **6670** are formed from separate components having different material properties. For example, the expandable portions **6640** can be formed from a material having a greater amount of flexibility, while the outer shell **6670** can be formed from a more rigid material. In this manner, the expandable portions **6640** can be easily moved from the collapsed configuration to the expanded configuration, while the outer shell **6670** is sufficiently strong to resist undesirable deformation when in use.

FIG. **103** is a flow chart illustrating a method according to an embodiment of the invention. A method includes at **6060**, percutaneously disposing an expandable member at a first location between adjacent spinous processes within a body of a patient while the expandable member is in a collapsed configuration. The expandable member is coupled to a deployment tool that includes an engaging portion configured to be received through an opening defined by the expandable member. In other embodiments, the deployment tool can be coupled to the implant after the implant has been disposed between the spinous processes. After the implant has been disposed between the adjacent spinous processes, the expandable member can be moved from the collapsed configuration to an expanded configuration at **6062**. To do this, the deployment tool can be actuated while the expandable member is disposed between the adjacent spinous processes such that the engaging portion of the deployment tool imparts a force to a first location on the expandable member and causes the expandable member to move from the collapsed configuration to an expanded configuration. After actuating the deployment tool such that the expandable member is moved from the collapsed configuration to the expanded configuration, the deployment tool can optionally be removed from the expandable member, at **6064**. In embodiments where the deployment tool has been removed, the deployment tool can be subsequently reinserted into the expandable member.

At **6066**, after the deployment tool has been actuated to move the implant from the collapsed configuration to the expanded configuration, the deployment tool can be actuated again such that the engaging portion imparts a force to a second location on the expandable member different from the first location on the expandable member, and the implant is moved from the expanded configuration to the collapsed configuration.

After actuating the deployment tool such that the expandable member is moved from the expanded configuration to the collapsed configuration, the expandable member can optionally be disposed at a second location between the adjacent spinous processes different from the first location, at **6068**. In some embodiments, after the deployment tool is actuated such that the expandable member is moved from the expanded configuration to the collapsed configuration, the expandable member can optionally be disposed at a second location outside of the body of the patient, at **6070**.

The various implants and deployment tools described herein can be constructed with various biocompatible materials such as, for example, titanium, titanium alloyed, surgical steel, biocompatible metal alloys, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, biocompatible polymeric materials, etc. The material of a central portion of the implant can have, for example, a compressive strength similar to or higher than that of bone. In one embodiment, the central portion of the implant, which is placed between the two adjacent spinous processes, is configured with a material having an elastic modulus higher than the elastic modulus of the bone, which forms the spinous processes. In another embodiment, the central portion of the implant is configured with a material having a higher elastic modulus than the materials used to configure the distal and proximal portions of the implant. For example, the central portion of the implant may have an elastic modulus higher than bone, while the proximal and distal portions have a lower elastic modulus than bone. In yet another embodiment, where the implant is configured with an outer shell and an inner core. The outer shell can be configured with material having a higher elastic modulus than the inner core (e.g., outer shell is made with titanium alloyed, while the inner core is made with a polymeric material). Alternatively, the outer shell can be configured with a material having a lower elastic modulus than the inner core (e.g., the outer shell is made with a polymeric material while the inner core is made with a titanium alloyed material).

An apparatus includes an elongate member having a proximal portion configured to be repeatedly moved between a first configuration and a second configuration under, for example, an axial load or a radial load. The elongate member has a distal portion configured to be moved from a first configuration to a second configuration under, for example, an axial load or a radial load. A non-expanding central portion is positioned between the proximal portion and the distal portion. The non-expanding central portion is configured to engage adjacent spinous processes upon spinal extension.

In some embodiments, the elongate member can have multiple portions that each move from a first configuration to a second configuration, either simultaneously or serially. Additionally, the device, or portions thereof, can be configured into many intermediate positions during the movement between the first configuration and the second configuration. For ease of reference, the entire device is referred to as being in either a first configuration or a second configuration although it should be understood that the device and/or portions thereof have a range of motion that includes many configuration including the first configuration and the second configuration.

FIG. **104** is a schematic illustration of a medical device according to an embodiment of the invention adjacent two adjacent spinous processes. The medical device **7010** includes a proximal portion **7012**, a distal portion **7014** and a central portion **7016**. The medical device **7010** has a first configuration in which it can be inserted between adjacent spinous processes S or removed from between adjacent spinous processes S. The central portion **7016** is configured to contact the spinous processes S to prevent over-extension/compression of the spinous processes S. In some embodiments, the central portion **7016** does not substantially distract the adjacent spinous processes S. In other embodiments, the central portion **7016** does not distract the adjacent spinous processes S. The medical device **7010** is inserted into a patient's back and moved in between adjacent spinous processes from the side of the spinous processes (i.e., a posterior-lateral approach). The use of a curved insertion shaft assists in the use of a lateral approach to the spinous processes S.

In the first configuration, the proximal portion **7012**, the distal portion **7014** and the central portion **7016** share a common longitudinal axis. In other embodiments, these portions do not share a common longitudinal axis. In some embodiments, the proximal portion **7012**, the distal portion **7014** and the central portion **7016** define a tube having a constant inner diameter. In other embodiments, the proximal portion **7012**, the distal portion **7014** and the central portion **7016** define a tube having a constant outer diameter and/or inner diameter. In yet other embodiments, the proximal portion **7012**, the distal portion **7014** and/or the central portion **7016** have different inner diameters and/or outer diameters.

The medical device **7010** can be moved from the first configuration to a second configuration as illustrated in FIG. **105**. In the second configuration, the proximal portion **7012** and the distal portion **7014** are positioned to limit lateral movement of the device **7010** with respect to the spinous processes S. The proximal portion **7012** and the distal portion **7014** are configured to engage the spinous process (i.e., either directly or through surrounding tissue) in the second configuration. For purposes of clarity, the tissue surrounding the spinous processes S is not illustrated. Note the medical device and/or its portions can engage the spinous processes S during all or just a portion of the range of motion of the spinous processes S associated with the patient's movements.

In some embodiments, the proximal portion **7012**, the distal portion **7014** and the central portion **7016** are monolithically formed. In other embodiments, one or more of the proximal portion **7012**, the distal portion **7014** and the central portion **7016** are separate components that can be coupled together to form the medical device **7010**. For example, the proximal portion **7012** and distal portion **7014** can be monolithically formed and the central portion **7016** can be a separate component that is coupled thereto. The proximal portion **7012**, the distal portion **7014** and the central portion **7016** can be the same or different materials. These various portions can be coupled, for example, by a friction fit, welding, adhesive, etc.

In use, the spinous processes S can be distracted prior to inserting the medical device **7010**. Distraction of spinous processes is described herein. When the spinous processes are distracted, a trocar can be used to define an access passage for the medical device **7010**. In some embodiments, the trocar can be used to define the passage as well as distract the spinous processes S. Once an access passage is defined, the medical device **7010** is inserted percutaneously and advanced between the spinous processes, distal end **7014** first, until the central portion **7016** is located between the spinous processes S. Once the medical device **7010** is in place between the spinous processes, the proximal portion **7012** and the distal portion **7014** are moved to the second configuration, either serially or simultaneously.

In some embodiments, the medical device **7010** is inserted percutaneously (i.e., through an opening in the skin) and in a minimally-invasive manner. For example, as discussed in detail herein, when inserted, the sizes of portions of the implant are smaller than the size of the opening. The sizes of portions of the implant are expanded after the implant is inserted between the spinous processes. Once expanded, the sizes of the expanded portions of the implant are greater than the size of the opening. When collapsed, the sizes of portions of the spinal implant are again smaller than the size of the opening. For example, the size of the opening/incision in the skin can be between 3 millimeters in length and 25 millimeters in length across the opening. In some embodiments, the size of the implant in the expanded configuration is between 3 and 25 millimeters across the opening.

In some embodiments, the proximal portion **7012** and the distal portion **7014** can be moved back to their original configuration or substantially close to their original configuration and either repositioned between the adjacent spinous processes or removed from the body in which they were inserted.

FIG. **106** is a schematic illustration of a deformable element **7018** that is representative of the characteristics of, for example, the distal portion **7014** of the medical device **7010** in a first configuration. The deformable member **7018** includes cutouts A, B, C along its length to define weak points that allow the deformable member **7018** to deform in a predetermined manner. Depending upon the depth d of the cutouts A, B, C and the width w of the throats T**1**, T**2**, T**3**, the manner in which the deformable member **7018** deforms under an applied load can be controlled and varied. Additionally, depending upon the length L between the cutouts A, B, C (i.e., the length of the material between the cutouts), the manner in which the deformable member **7018** deforms can be controlled and varied.

FIG. **107** is a schematic illustration of the expansion properties of the deformable member **7018** illustrated in FIG. **106**. When a load is applied, for example, in the direction indicated by arrow X, the deformable member **7018** deforms in a predetermined manner based on the characteristics of the deformable member **7018** as described above. As illustrated in FIG. **107**, the deformable member **7018** deforms most at cutouts B and C due to the configuration of the cutout C and the short distance between cutouts B and C. In some embodiments, the length of the deformable member **7018** between cutouts B and C is sized to fit one side of adjacent spinous processes.

The deformable member **7018** is stiffer at cutout A due to the shallow depth of cutout A. As indicated in FIG. **107**, a smooth transition is defined by the deformable member **7018** between cutouts A and B. Such a smooth transition causes less stress on the tissue surrounding a side of adjacent spinous processes than a more drastic transition (i.e., a steeper angled wall) such as between cutouts B and C. The dimensions and configuration of the deformable member **7018** can also determine the timing of the deformation at the various cutouts. The weaker (i.e., deeper and wider) cutouts deform before the stronger (i.e., shallower and narrower) cutouts.

FIGS. **108** and **109** illustrate a spinal implant **7100** in a first configuration and second configuration, respectively. As shown in FIG. **108**, the spinal implant **7100** is collapsed in a first configuration and can be inserted between adjacent spinous processes. The spinal implant **7100** has a first deformable portion **7110**, a second deformable portion **7120** and a central, non-deformable portion **7150**. The first deformable portion **7110** has a first end **7112** and a second end **7114**. The second deformable portion **7120** has a first end **7122** and a second end **7124**. The central portion **7150** is coupled between second end **7114** and first end **7122**. In some embodiments, the spinal implant **7100** is monolithically formed.

The first deformable portion **7110**, the second deformable portion **7120** and the central portion **7150** have a common longitudinal axis A along the length of spinal implant **7100**. The central portion **7150** can have the same inner diameter as first deformable portion **7110** and the second deformable portion **7120**. In some embodiments, the outer diameter of the central portion **7150** is smaller than the outer diameter of the first deformable portion **7110** and the second deformable portion **7120**.

In use, spinal implant **7100** is inserted percutaneously between adjacent spinous processes. The first deformable portion **7110** is inserted first and is moved past the spinous processes until the central portion **7150** is positioned between the spinous processes. The outer diameter of the central portion **7150** can be slightly smaller than the space between the spinous processes to account for surrounding ligaments and tissue. In some embodiments, the central portion **7150** directly contacts the spinous processes between which it is positioned. In some embodiments, the central portion of spinal implant **7100** is a fixed size and is not compressible or expandable. Note the spinal implant **7100** and/or the first deformable portion **7110**, second deformable portion **7120**, and central portion **7150** can engage the spinous processes during all or just a portion of the range of motion of the spinous processes associated with the patient's movement.

The first deformable portion **7110** includes, for example, expanding members **7115**, and **7117**. Between the expanding members **7115**, **7117**, openings (not illustrated) are defined. As discussed above, the size and shape of the openings influence the manner in which the expanding members **7115**, **7117** deform when an axial load is applied. The second deformable portion **7120** includes expanding members **7125** and **7127**. Between the expanding members **7125**, **7127**, openings (not illustrated) are defined. As discussed above, the sizes and shapes of the openings influence the manner in which the expanding members **7125**, **7127** deform when an axial load is applied.

When an axial load is applied to the spinal implant **7100**, the spinal implant **7100** expands to a second configuration as illustrated in FIG. **109**. In the second configuration, first end **7112** and second end **7114** of the first deformable portion **7110** move towards each other and expanding members **7115**, **7117** project substantially laterally away from the longitudinal axis A. Likewise, first end **7122** and second end **7124** of the second deformable portion **7120** move towards one another and expanding members **7125**, **7127** project laterally away from the longitudinal axis A. The expanding members **7115**, **7117**, **7125**, **7127** in the second configuration form projections that extend to positions adjacent to the spinous processes between which the spinal implant **7100** is inserted. In the second configuration, the expanding members **7115**, **7117**, **7125**, **7127** inhibit lateral movement of the spinal implant **7100**, while the central portion **7150** prevents the adjacent spinous processes from moving together any closer than the distance defined by the diameter of the central portion **7150** during spinal extension.

The first end **7112** of the first deformable portion **7110** defines a threaded opening **7113**. The central portion **7150** defines a second threaded opening **7155**. The second end **7124** of the second deformable portion **7120** defines a third threaded opening **7123**. The threaded openings **7113**, **7155**, **7123** receive portions of an actuator **7200** (see FIG. **110**) to move the first deformable portion **7100** and the second deformable portion **7120** between their respective first configurations and second configurations as described in greater detail herein. In some embodiments, the first threaded opening **7113** has a greater diameter than the second threaded opening **7155** and the third threaded opening **7123** (see FIGS. **108-111**). In some embodiments the second threaded opening **7155** and the third threaded opening **7123** have the same diameter (see FIGS. **108-111**). In other embodiments, the first threaded opening **7113'** and the second threaded opening **7155'** have the same diameter (see FIGS. **112-115**) and the third threaded opening **7123'** has a smaller diameter than the first threaded opening and the second threaded opening. The threaded openings **7113**, **7155**, **7123**, **7113'**, **7155'**, **7123'** are coaxially aligned. In other embodiments, the threaded openings can be any combination of different or the same sizes.

The spinal implant **7100** is deformed by a compressive force imparted substantially along the longitudinal axis A of the spinal implant **7100**. As illustrated in FIG. **110**, the compressive force is imparted to the first deformable portion **7110** by actuator **7200**. The actuator includes a first portion **7210** and a second portion **7220** movably received within first portion **7210**. In some embodiments, the second portion **7220** is slidably received within the first portion **7210**. In other embodiments, the first portion **7210** and the second portion **7220** are threadedly coupled. Each of the first portion **7210** and the second portion **7220** is provided with external threads **7212** and **7222**, respectively, to engage the threaded openings **7113**, **7155**, **7123**, **7113'**, **7155'**, **7123'**.

As illustrated in FIG. **110**, the compressive force is imparted to the first deformable portion **7110**, for example, by attaching the threaded portion **7212** to the first threaded opening **7113**, attaching the threaded portion **7222** to the second threaded opening **7155** of the central portion **7150**, and drawing the second portion **7220** along the longitudinal axis A while imparting an opposing force against the first end **7112** of the first deformable portion **7110**. The opposing force results in a compressive force causing the spinal implant **7100** to expand as discussed above.

Once the first deformable portion **7110** is moved to its second configuration, the threaded portion **7222** is threaded through the second threaded opening **7155** and threadedly coupled to the third threaded opening **7123**. A compressive force is imparted to the second deformable portion **7120** of the spinal implant **7100** by drawing the second portion **7220** of the actuator in the direction indicated by the arrow F while applying an opposing force using the first portion **7210** of the actuator against the spinal implant **7100**. The opposing forces result in a compressive force causing the spinal implant to expand as illustrated in FIG. **111**.

In some embodiments, the first deformable portion **7110** and the second deformable portion **7120** can be expanded simultaneously when the second portion **7220** of the actuator is coupled to the third threaded opening **7123** and the first portion **7210** is coupled to the first threaded opening **7113** and a compressive force is applied.

In embodiments in which the first threaded opening **7113'** has the same diameter as the second threaded opening **7155'** (best seen, for example, in FIGS. **112** and **113**), the first threaded portion **7212** can be threadedly coupled to the second threaded opening **7155'** and the second threaded portion **7222** can be threadedly coupled to the third threaded opening **7123'**. A compressive force is then applied between the central portion **7150** and the second end **7124** of the second deformable portion **7120**. Once the second deformable portion **7120** is in its second configuration, the first threaded portion **7212** can be threadedly coupled to the first threaded opening **7113'** and the first deformable portion **7110** can be deformed into its second configuration.

After each of the first deformable portion **7110** and the second deformable portion **7120** are moved to the second expanded configuration, they subsequently can each be moved back to the first collapsed configuration by applying a force in the opposite direction along longitudinal axis A as illustrated, for example, in FIGS. **114-115**. In this example, as discussed above, the spinal implant **7100** illustrated in FIGS. **112-115** has a first threaded opening **7113'** that has the same diameter as the second threaded opening **7155'**.

With the first threaded portion **7212** coupled to the second threaded opening **7155'** and the second threaded portion **7222** coupled to the third threaded opening **7123'**, the second portion **7220** of the actuator **7200** is moved in the direction indicated by arrow F to move the second deformable portion **7120** to its first collapsed configuration.

The first threaded portion **7212** is then coupled to the first threaded opening **7113'** and the second portion **7220** of actuator **7200** is again moved in the direction of arrow F to move the first deformable portion **7110** to its first collapsed configuration. When the entire spinal implant **7100** has been completely collapsed, the spinal implant **7100** can be repositioned between the spinous processes, or removed from its position between the spinous processes and removed from the body in which it was previously inserted. In some embodiments, the first deformable portion **7110** and the second deformable portion **7120** are not completely collapsed, but are instead moved to a configuration between fully expanded and fully collapsed. In this manner the spinal implant **7100** may be repositioned or removed without being completely collapsed.

In some embodiments, the first deformable portion **7110** and the second deformable portion **7120** can be moved between the first and second configuration using a balloon as an actuator. As illustrated in FIG. **116**, the second deformable portion **7120** is then moved from the second configuration to the first configuration by imparting a longitudinal force resulting from the inflation of a balloon **7300** with liquid and/or gas. As the balloon **7300** is inflated, it is forced against the central portion **7150** and the second end **7124** of the second deformable portion **7120**. The force imparted by the balloon **7300** is generally in the direction indicated by the arrow F. In some embodiments, the balloon **7300** is a low-compliant balloon that is configured to expand to a predefined shape such that a force is imparted primarily in a substantially longitudinal direction indicated by arrow F.

After the second deformable portion **7120** is moved substantially to its collapsed configuration, the balloon **7300** is deflated and moved into the first deformable portion **7110**. The balloon **7300** is then inflated as illustrated in FIG. **117** to impart a force in the direction indicated by arrow F. In some embodiments, the same balloon **7300** is used to collapse both the first deformable portion **7110** and the second deformable portion **7120**. In other embodiments, a different balloon is used for each portion **7110**, **7120**. Once the entire implant **7100** is moved to the first configuration, the balloon is deflated and removed. In some embodiments, the balloon **7300** remains in the spinal implant **7100**, and the spinal implant **7100** and the balloon **7300** are removed simultaneously.

In some embodiments, the shaft on which the balloon is coupled has external threads (not illustrated) to mate with the first threaded opening **7113**, **7113'** and/or the second threaded opening **7155**, **7155'**. In other embodiments, neither the openings nor the shaft on which the balloon is coupled are threaded. In yet other embodiments, the balloon **7300** is inserted through the first portion **7210** of the actuator **7200**. Alternatively, the actuator **7200** and the balloon **7300** can be used in conjunction with the spinal implant to expand and/or contract the first deformable portion **7110** and the second deformable portion **7120**.

In other embodiments, there are no threaded openings defined in the spinal implant **7100**. For example, the spinal implant can have multiple actuator-engaging portions that are not threaded, but are rather contact or bearing surfaces for various types of actuators. For example, an actuator (not illustrated) can be configured to grasp an outer surface of the spinal implant while simultaneously imparting a force against the distal portion of the spinal implant to move the implant to a collapsed configuration.

The spinal implant **7100** can be made from, for example, stainless steel, plastic, polyetheretherketone (PEEK), carbon fiber, ultra-high molecular weight (UHMW) polyethylene, etc. or some combination thereof. For example, the first deformable portion and the second deformable portion can be made from one material and the non-expanding central portion can be made from a different material. The material of such a non-expanding central portion can have a tensile strength similar to or higher than that of bone.

As described above, in some embodiments, the spinal implants shown and described above can be inserted between adjacent spinous processes percutaneously using a posterior-lateral approach. FIGS. **133** and **134** show an implant **8100** and a portion of an insertion tool **8500** being inserted into a body B using a posterior-lateral approach according to an embodiment of the invention. The body B includes spinous processes SP**1**-SP**4**, which define a mid-line axis L_M. A lateral axis L_L is defined substantially normal to the mid-line axis L_M.

To position the implant **8100** between adjacent spinous processes SP**2** and SP**3**, a lateral incision I having a length Y**2** is made a distance X from the mid-line axis L_M. The length Y**2** and the distance X can be selected to allow the implant to be inserted percutaneously in a minimally-invasive manner. In some embodiments, the distance X can be, for example, between 25 mm and 100 mm. In some embodiments, the incision I has a length Y**2** that is no greater than the distance Y**1** between the adjacent spinous processes, such as, for example, SP**2** and SP**3**. In some embodiments, for example, the length Y**2** is no greater than 15 mm and the distance Y**1** is between 20 mm and 25 mm. In other embodiments, the length Y**2** can exceed the distance Y**1** between the adjacent spinous processes SP**2** and SP**3**. In some embodiments, for example, the length Y**2** can be as much as 50 mm.

A distraction tool (not shown in FIGS. **133** and **134**) is then inserted through the incision I and is used to define the passageway P from the incision I to the adjacent spinous processes SP**2** and SP**3**. The distraction tool can also distract the adjacent spinous processes SP**2** and SP**3** to define the desired space between, as described above. The distraction tool can be any suitable distraction tool, such as for example, distraction tool **2010** shown and described with reference to FIG. **48**.

The insertion tool **8500** including the implant **8100** is then inserted through the incision I and via the passageway P to the space between the adjacent spinous processes SP**2** and SP**3**. The implant **8100** is then disposed between the adjacent spinous processes SP**2** and SP**3** in any suitable manner, as described above. For example, in some embodiments, the implant **8100** can include one or more expandable portions that are adjacent to and/or engage portions of the spinous processes SP**2** and/or SP**3** to limit at least a lateral movement of the implant **8100**.

As shown in FIGS. **133** and **134**, during the insertion operation, the insertion tool **8500** is positioned such that when the implant **8100** is disposed between the adjacent spinous processes SP**2** and SP**3**, the implant **8100** is substantially aligned with the lateral axis L_L. Said another way, during insertion, the insertion tool **8500** is positioned such that the longitudinal axis (not shown) of the implant **8100** is substantially coaxial with the lateral axis L_L. As described in more detail herein, the insertion tool **8500** is configured to ensure that the implant **8100** is aligned with the lateral axis L_L during insertion.

As shown in FIGS. **135** and **136**, the insertion tool **8500**, which can be similar to the insertion tools **1500** and **7500** shown and described above, includes a curved portion **8520** and an implant support portion **8530**. The insertion tool **8500** defines a center line CL. As shown in FIGS. **135** and **136**, which show a side view and a top plan view, respectively, of the insertion tool **8500**, the center line CL of the curved portion **8520** defines a radius of curvature R**1** about an axis A**1** that is substantially normal to the center line CL. The radius of curvature R**1** can be any value suitable to define and/or proceed along the passageway P such that the implant **8100** and/or a portion of the center line CL is aligned with the lateral axis L_L during insertion. Moreover, the radius of curvature R**1** can be selected to blend with the adjacent portions of the insertion tool **8500** to ensure that the surface of the insertion tool **8500** is continuous.

In some embodiments, for example, an insertion tool **8500** can have a small radius of curvature R**1** (e.g., 20 mm to 50 mm), which corresponds to a relatively sharp curve. Such an embodiment can be appropriate, for example, when the distance X between the incision I and the mid-line axis L_M is relatively small (e.g. 20 mm), requiring that passageway P have a relatively sharp curve to ensure that the implant **8100** is properly aligned. In other embodiments, for example, an insertion tool **8500** can have a large radius of curvature R**1** (e.g., greater than 300 mm), which corresponds to less curvature. Such an embodiment can be appropriate, for example, when the distance X between the incision I and the mid-line axis L_M is relatively great (e.g. greater than 50 mm). In yet other embodiments, an insertion tool **8500** can have a radius of curvature R**1** that is between 50 mm and 300 mm. In some embodiments, for example, an insertion tool **8500** can have a radius of approximately 181 mm.

Although the insertion tool **8500** is shown and described as having a single radius of curvature R**1**, in some embodiments, an insertion tool can have multiple radii of curvature and/or geometrically complex shapes. For example, FIGS. **137** and **138** show a side view and a top plan view of an insertion tool **9500** according to an embodiment of the invention. The insertion tool **9500** includes a curved portion **9520** and an implant support portion **9530**. A center line CL of the curved portion **9520** defines a first radius of curvature R**1** about a first axis A**1** that is substantially normal to the center line CL. The center line CL of the curved portion **9520** also defines a second radius of curvature R**2** about a second axis A**2** that is substantially parallel to the first axis A**1** and substantially normal to the center line CL. As described above, the radii of curvature R**1** and R**2** can be any value suitable to define the passageway P such that the implant is aligned with the lateral axis L_L during insertion. Moreover, as shown in FIG. **137**, a portion of the elongate member **9500** is disposed between the first axis A**1** and the second axis A**2**. Said another way, the first axis A**1** and the second axis A**2** are positioned such that the curved portion **9520** forms an "S" shape.

Although the insertion tool **9500** is shown and described as defining axis A**1** and axis A**2** with insertion tool **9500** therebetween, in other embodiments, an insertion tool can be on the same side of these axes. Similarly, although the insertion tool **9500** is described as defining axes A**1** and A**2** that are substantially parallel to each other, in other embodiments, as described in more detail below, an insertion tool can define axes A**1** and A**2** that are not substantially parallel to each other. Said another way, although the insertion tool **9500** is shown as having a two-dimensional curve, in other embodiments, an insertion tool can have a three-dimensional curve.

Although FIGS. **133** and **134** illustrate a single-level insertion (i.e., one spinal implant inserted between a pair of adjacent spinous processes), in some embodiments, the insertion tool **8500** can be used to insert multiple implants between multiple pairs of adjacent spinous processes through a single incision. FIG. **139** shows an example of a multi-level insertion operation according to an embodiment of the invention. FIG. **139** shows a body B having an two implants **8100**A and **8100**B disposed therein using a posterior-lateral approach through a single incision I'. The body B includes spinous processes SP**1**-SP**5**, which define a mid-line axis L_M. A first lateral axis L_{L1} is defined substantially normal to the mid-line axis L_M and centered within the space between the first pair of spinous processes SP**2** and SP**3**. Similarly, a second lateral axis L_{L2} is defined substantially normal to the mid-line axis L_M and centered within the space between the second pair of spinous processes SP**3** and SP**4**.

To position the implants **8100**A and **8100**B between the first pair of spinous processes SP**2** and SP**3** and the second pair of spinous processes SP**3** and SP**4**, a lateral incision I' having a length Y**2'** is made a distance X' from the mid-line axis L_M. As shown, the lateral incision I' is offset from the space between the first pair of spinous processes SP**2** and SP**3** and from the space between the second pair of spinous processes SP**3** and SP**4**. Said another way, the lateral incision I' is offset from the first lateral axis L_{L1} and the second lateral axis L_{L2}. As described above, the length Y**2'** and the distance X' can be selected to allow the implant to be inserted percutaneously in a minimally-invasive manner. Additionally, the length Y**2'** and the distance X' can be selected to reduce or minimize the lateral offset angles α**1** and α**2**.

In some embodiments, the distance X' can be, for example, between 25 mm and 100 mm. In some embodiments, the length Y2' is no greater than the distance between adjacent spinous processes. In some embodiments, for example, the length Y2' is no greater than 15 mm. In other embodiments, the length Y2' can exceed the distance between adjacent spinous processes. In some embodiments, for example, the length Y2' can be as much as 50 mm.

A first distraction tool (not shown in FIG. **139**) is then inserted through the incision I' and is used to define a first passageway P**1** from the incision I' to the first pair of spinous processes SP**2** and SP**3**. The first distraction tool can also distract the adjacent spinous processes SP**2** and SP**3** to define the desired space between, as described above. A first insertion tool (not shown in FIG. **139**) is then inserted through the incision I' and via the first passageway P**1** to the space between the first pair of spinous processes SP**2** and SP**3**. The implant **8100**A is then disposed between the first pair of spinous processes SP**2** and SP**3** in any suitable manner, as described above.

Similarly, a second distraction tool (not shown in FIG. **139**) is inserted through the incision I' and is used to define a second passageway P**2** from the incision I' to the second pair of spinous processes SP**3** and SP**4**. The second distraction tool can also distract the adjacent spinous processes SP**3** and SP**4** to define the desired space between, as described above. In some embodiments, the second distraction tool can be identical to the first distraction tool (e.g., the multi-level operation is completed using two identical tools). In other embodiments, the second distraction tool can be different from the first distraction tool. In such embodiments, for example, the second distraction tool may have a different radius of curvature, which can result in the second passageway P**2** being different from the first passageway P**1**. In yet other embodiments, the multi-level operation can be completed using a single distraction tool.

A second insertion tool (not shown in FIG. **139**), is then inserted through the incision I' and via second passageway P**2** to the space between the second pair of spinous processes SP**3** and SP**4**. The implant **8100**B is then disposed between the second pair of spinous processes SP**3** and SP**4** in any suitable manner, as described above. In this manner, a multi-level insertion can be made through a single incision. As described above for the distraction tools, in some embodiments, the second insertion tool can be identical to the first insertion tool. In other embodiments, the second insertion tool can be different from the insertion distraction tool. In yet other embodiments, the multi-level operation can be completed using a single insertion tool.

As discussed above, during the multi-level insertion operation shown in FIG. **139**, the implants **8100**A and **8100**B can be positioned to reduce or minimize the lateral offset angles $\alpha\mathbf{1}$ and $\alpha\mathbf{2}$. The lateral offset angles $\alpha\mathbf{1}$ and $\alpha\mathbf{2}$ are defined by the angular offset between the longitudinal axes LA and LB of the implants **8100**A and **8100**B and the lateral axes L_{L1} and L_{L2}. As the offset angles $\alpha\mathbf{1}$ and $\alpha\mathbf{2}$ decrease, the degree of alignment between the implants **8100**A and **8100**B and the lateral axes L_{L1} and L_{L2} increases. For example, in embodiments in which the lateral offset angles are substantially zero, the implants **8100**A and **8100**B are substantially aligned with the lateral axes L_{L1} and L_{L2}.

The position of the implants **8100**A and **8100**B can be a function of many parameters. For example, in some embodiments, the position of the implants **8100**A and **8100**B can be adjusted by increasing or decreasing the distance X' and/or the length Y2' of the incision I'. In other embodiments, the position implants **8100**A and **8100**B can be adjusted by placing the implants **8100**A and **8100**B within the body B using distraction tools and/or insertion tools configured to align substantially the implants **8100**A and **8100**B with their respective lateral axes L_{L1} and L_{L2}. For example, in some embodiments, the first insertion tool and the second insertion tool can have curved portions corresponding to the desired shape of the passageways P**1** and P**2**. In some embodiments, the curved portion of the first insertion tool and the curved portion of the second insertion tool each can be similar to the curved portion **8520** of the insertion tool **8500** shown in FIG. **135**.

FIGS. **140** and **141** show a multi-level insertion operation according to an embodiment of the invention in which the distraction tools and/or insertion tools are configured to define a passageways having a three-dimensional curved shape. The embodiment shown in FIG. **140** is similar to the embodiment shown in FIG. **139** and will therefore not be described in great detail. FIG. **140** shows a body B having an two implants **8100**A and **8100**B disposed therein using a posterior-lateral approach through a single incision I". The body B includes spinous processes SP**1**-SP**5**, which define a mid-line axis L_M. A first lateral axis L_{L1} is defined substantially normal to the mid-line axis L_M and centered within the space between the first pair of spinous processes SP**2** and SP**3**. Similarly, a second lateral axis L_{L2} is defined substantially normal to the mid-line axis L_M and centered within the space between the second pair of spinous processes SP**3** and SP**4**.

To position the implants **8100**A and **8100**B within the body B, a lateral incision I' having a length Y**2**" is made a distance X" from the mid-line axis L_M. A first distraction tool (not shown in FIG. **139**) is then inserted through the incision I' and is used to define a first passageway P**1**" having a three-dimensional curved shape. Said another way, the first passageway P**1**" has a curved shape when viewed from a posterior perspective (FIG. **140**) and when viewed from a side perspective (FIG. **141**). In this manner, the implant **8100**A can be aligned substantially with the lateral axis. A first insertion tool (not shown in FIGS. **140** and **141**) is then inserted through the incision I" and via the first passageway P**1**" to the space between the first pair of spinous processes SP**2** and SP**3**. The implant **8100**A is then disposed between the first pair of spinous processes SP**2** and SP**3** in any suitable manner, as described above.

Similarly, a second distraction tool (not shown in FIGS. **140** and **141**) is inserted through the incision I" and is used to define a second passageway P**2**" having a three-dimensional curved shape. A second insertion tool (not shown in FIGS. **140** and **141**), is then inserted through the incision I" and via second passageway P**2**" to the space between the second pair of spinous processes SP**3** and SP**4**. The implant **8100**B is then disposed between the second pair of spinous processes SP**3** and SP**4** in any suitable manner, as described above.

Although the insertion tools and/or distraction tools are shown and described above as including two-dimensional curved portions (i.e., the tool is substantially linear when shown in a top plan view, as in FIG. **136**, for example), in some embodiments, an insertion tool can have a three-dimensional curvature. As described above with reference to FIGS. **140** and **141**, a three-dimension curvature can be used, for example, to promote the alignment of an implant with the lateral axis in a side view (see e.g., FIG. **141** showing the depth alignment of the implant) and in a top plan view (see e.g., FIGS. **139** and **140** showing the offset angle alignment of the implants). FIGS. **142** and **143** show a side view and a top plan view, respectively, of an insertion tool **10500** according to an embodiment of the invention. The insertion tool **10500** includes a curved portion **10520** and an implant support portion **10530**. The insertion tool **10500** defines a center line CL. The center line CL of the curved portion **10520** defines a first radius of curvature R**1** about a first axis A**1** that is substantially normal to the center line CL. The center line CL of the curved portion **10520** also defines a second radius of curvature R**2** about a second axis A**2** that is substantially normal to the first axis A**1** and substantially normal to the center line CL. In this manner, the insertion tool **10500** has a three-dimensional curved portion **10520**. As described above, the radii of curvature R**1** and R**2** can be any value suitable to define the passageway within the body such that the implant is aligned with the lateral axis during insertion.

Although the multi-level insertion operations are shown and described above as including placing two implants between two pairs of adjacent spinous processes, in some embodiments, a multi-level insertion operation can include placing three or more implants between three or more pairs of adjacent spinous processes through a single incision. For example, FIG. **144** shows a posterior view of a multi-level insertion operation in which three implants are disposed within the body B. As shown, the body B includes spinous processes SP**1**-SP**5**, which define a mid-line axis L_M. As described above, the operation includes using three distraction and/or insertion tools to define three passageways P**1'''**, P**2'''** and P**3'''** between an incision I''' and the desired interspinous space. As described above, the passageways can have any suitable shape to promote alignment of the spinal implants during the insertion operation.

FIG. **145** is a flow chart of a method **10000** for inserting a spinal implant according to an embodiment of the invention. The illustrated method includes making an incision having a size no greater than a distance between adjacent spinous processes, **10002**. In some embodiments, for example, the incision can be a lateral incision having a length of 15 mm or less. A first support member, such as, for example, a spinal implant of the type shown and described above, is inserted through the incision, **10004**. The first support member can be inserted using an insertion tool of the type shown and described above. The first support member is then disposed between a first pair of adjacent spinous processes, **10006**. A second support member is inserted through the incision, **10008**. As described above, in some embodiments, the second support member can be inserted using an insertion tool having a different shape than the insertion tool used to insert the first support member. In other embodiments, the insertion tool used to insert the first support member can be identical to the insertion tool used to insert the second support member. In yet other embodiments, the first support member and the second support member can be inserted using a single insertion tool. The second support member is then disposed between a second pair of adjacent spinous processes, **10010**.

In some embodiments, the first pair of spinous processes is adjacent the second pair of spinous processes. Said another way, as shown in FIG. **139**, the first pair of spinous processes can overlap the second pair of spinous processes in that there is a common spinous process (SP**3** in FIG. **139**) between the pairs. In other embodiments, the first pair of spinous processes can be offset from the second pair of spinous processes in that there is no overlap between the pairs.

FIG. **146** is a flow chart of a method **10020** according to an embodiment of the invention. The illustrated method includes making an incision having a size no greater than approximately half a distance between adjacent spinous processes, **10022**. A first tool, such as, for example, an insertion or a distraction tool of the type shown and described above, is inserted through the incision to define a first passageway, **10024**. A first support member is then disposed between a first pair of adjacent spinous processes via the first passageway, **10026**. In some embodiments, for example, the tool used to define the first passageway can be different than the tool used to dispose the support member between the first pair of spinous processes. In other embodiments, the first tool can define the first passageway and dispose the first support member between the first pair of spinous processes.

A second tool is inserted through the incision to define a second passageway, **10028**. A second support member is then disposed between a second pair of adjacent spinous processes via the second passageway, **10030**. Similarly, in some embodiments, the second tool used to define the second passageway can be different than the tool used to dispose the second support member between the second pair of spinous processes. In other embodiments, however, the second tool can both define the second passageway and dispose the support member between the second pair of spinous processes.

While various embodiments of the invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art having the benefit of this disclosure would recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Thus, the breadth and scope of the invention should not be limited by any of the above-described embodiments, but should be defined only in accordance with the following claims and their equivalents. While the invention has been particularly shown and described with reference to specific embodiments thereof, it will be understood that various changes in form and details may be made.

For example, although the embodiments above are primarily described as being spinal implants configured to be positioned between adjacent spinous processes, in alternative embodiments, the implants are configured to be positioned adjacent any bone, tissue or other bodily structure where it is desirable to maintain spacing while preventing axial or longitudinal movement of the implant.

While the implants described herein were primarily described as not distracting adjacent spinous processes, in alternative embodiments, the implants can be configured to expand to distract adjacent spinous processes, or can be configured to distract upon insertion.

Although described as being inserted directly between adjacent spinous processes, in alternative embodiments, the implants described above can be delivered through a cannula.

For example, although the swing arm **1700** is described as having an arcuate portion, in alternative embodiments of the invention, the entire swing arm **1700** may have an arcuate configuration. Additionally, the opening defined in the swing arm **1700** may extend the entire length of the swing arm **1700**.

Although the swing arm **1700** is described and illustrated as having a circular opening at its end, in alternative embodiments, the opening can be any shape and the shape of the portion of the working tool and/or spacer can be shaped to engage matingly the opening of the swing arm.

Although the connection between the swing arm and the working tool are shown with the swing arm being the female component and the working tool being the male component, in alternative embodiments, the orientation of the male/female relationship may be reversed.

Although the first arm **1170** and second arm **1180** of the first clamp **1100** are described as being resiliently coupled, in alternative embodiments of the invention, the first arm **1170** and the second arm **1180** are pivotably or hingedly coupled.

Although the first clamp and second clamp are disclosed as having jaws that engage opposite sides of a spinous process, in alternative embodiments, the first clamp and second clamp may include other configurations to engage the spinous process such as, for example, suction, adhesive, pins/projections, etc.

While the first clamp and second clamp are disclosed as being movable with respect to one another, in alternative embodiments, the first clamp or the second clamp may be fixed in position, with the other clamp moving relative to the fixed clamp.

While the first arm and the second arm of the clamp are shown as being resiliently biased apart from one another, in alternative embodiments, the first arm and the second arm can be manually moved towards and away from one another using a different configuration (e.g., scissor configuration).

Although embodiments are disclosed that illustrate the wire being coupled to the swing arm using a retainer, in alternative embodiments, a retainer need not be used. The wire can be coupled to the swing arm using other retention methods, such as, for example, a slit in which the wire can be clamped.

Additionally, although the working tool **1840** is disclosed as a trocar tip, the working tool may be any working tool such as, for example, a spacer, a balloon actuator, a bone tamp, etc.

Although the actuator used to move the spinal implant from the expanded configuration to the collapsed configuration is described as a rod assembly or a balloon, in alternative embodiments the actuator can be any device configured to impart a longitudinal force sufficient to move the implant to its collapsed configuration. For example, the actuator can be a piston/cylinder assembly, a ratchet assembly, or the like.

Although the insertion tools **9500** and **10500** are shown and described as having a curved portion defining two radii of curvature, in other embodiments an insertion tool can have any number of curved portions defining any number of radii of curvature. For example, in some embodiments, an insertion tool can include a first curved portion, a second curved portion and a linear portion disposed therebetween.

Although the insertion tools are shown and described as having a curved portion and/or a complex geometrical shape, in some embodiments, a distraction tool can have a geometry and/or a shape similar to that described above with reference to the insertion tools.

What is claimed is:

1. A method, comprising:

positioning an implant having an end portion and a body portion such that the body portion is disposed between a pair of adjacent spinous processes; wherein the body portion and the end portion are in respective collapsed configurations during the positioning;

moving the body portion of the implant from its collapsed configuration to an expanded configuration at a first time after the positioning;

moving the end portion of the implant from its collapsed configuration to an expanded configuration at a second time after the positioning;

wherein the second time different than the first time and the first and second times do not overlap.

2. The method of claim **1**, wherein the positioning includes inserting percutaneously the implant into a patient's body through an opening having a size less than a distance between the pair of adjacent spinous processes.

3. The method of claim **1**, wherein the moving the body portion includes contacting the pair of adjacent spinous processes with at least a portion of the body portion of the implant.

4. The method of claim **1**, wherein the moving the body portion includes distracting the pair of adjacent spinous processes.

5. The method of claim **1**, wherein the moving the body portion includes at least one of inflating a portion of the body portion or deforming a portion of the body portion.

6. The method of claim **1**, wherein the expanded configuration of the body portion of the implant is a first expanded configuration, the method further comprising:

moving the body portion of the implant from the first expanded configuration to a second expanded configuration different from the first expanded configuration of the body portion at a third time after the positioning, the third time different from the first time and the second time.

7. The method of claim **1**, wherein the moving the end portion includes at least one of inflating a portion of the end portion or deforming a portion of the end portion.

8. The method of claim **1**, wherein at least one of the moving the body portion or the moving the end portion includes applying an axial load to the implant.

9. The method of claim **1**, wherein:

the moving the body portion of the implant is performed using a first actuator; and the moving the end portion of the implant is performed using a second actuator different from the first actuator.

10. A method, comprising:

positioning an implant having an end portion and a body portion such that the body portion is disposed at a position along a lateral insertion path between a pair of adjacent spinous processes; wherein the body portion and the end portion are in respective collapsed configurations during the positioning;

distracting the pair of adjacent spinous processes with the body portion of the implant while maintaining the body portion of the implant at the position along a lateral insertion path;

thereafter, moving the end portion of the implant from its collapsed configuration to an expanded configuration such that lateral movement of the implant relative to the pair of adjacent spinous processes is limited in at least one direction.

11. The method of claim **10**, wherein the positioning includes inserting percutaneously the implant into a patient's body through an opening having a size less than a distance between the pair of adjacent spinous processes.

12. The method of claim **10**, wherein the distracting includes moving the body portion of the implant from a collapsed configuration to an expanded configuration.

13. The method of claim **10**, wherein the distracting includes at least one of inflating a portion of the body portion or deforming a portion of the body portion.

14. The method of claim **10**, wherein the moving the end portion includes at least one of inflating at least a portion of the end portion or deforming at least a portion of the end portion.

15. The method of claim **10**, wherein the moving the end portion includes applying an axial load to the implant.

16. The method of claim **10**, wherein the end portion is a distal end portion, the direction is a first direction, the method further comprising: moving a proximal end portion of the implant from a collapsed configuration to an expanded configuration such that lateral movement of the implant relative to the pair of adjacent spinous processes is limited in a second direction opposite to the first direction.

17. A method, comprising:

positioning an implant having a first portion and a second portion such that at least a portion of the implant is disposed between a pair of adjacent spinous processes; wherein the first and second portions are in respective collapsed configurations during the positioning;

moving the first portion of the implant from a collapsed configuration to an expanded configuration using a first actuator after the positioning; and

moving the second portion of the implant from a collapsed configuration to an expanded configuration using a second actuator after the positioning, the second actuator different from the first actuator;

wherein an overall longitudinal length of the implant, from an end of the first portion opposite the second portion to the end of the second portion opposite the first portion; does not change during one of the moving the first portion to its expanded configuration and the moving the second portion to its expanded configuration;

wherein the overall longitudinal length of the implant changes during the other of the moving the first portion to its expanded configuration and the moving the second portion to its expanded configuration.

18. The method of claim **17**, wherein:

the moving the first portion is performed at a first time after the positioning; and

the moving the second portion is performed at a second time after the positioning, the second time different than the first time.

19. The method of claim **17**, wherein the positioning includes inserting percutaneously the implant into a patient's body through an opening having a size less than a size of the first portion in its expanded configuration and less than a size of the second portion in its expanded configuration.

20. The method of claim **17**, wherein the moving the first portion includes distracting the pair of adjacent spinous processes.

21. The method of claim **17**, wherein one of the moving the first portion to an expanded configuration and the moving the second portion to an expanded configuration comprises inflating the respective portion.

22. A method, comprising:

positioning an implant having a first portion and a second portion within a body such that at least a portion of the implant is disposed between a pair of adjacent spinous processes;

moving the first portion of the implant from a collapsed configuration to an expanded configuration using a first actuator after the positioning; and

moving the second portion of the implant from a collapsed configuration to an expanded configuration using a second actuator after the positioning, the second actuator different from the first actuator;

wherein the first actuator includes an inflation tube configured to be placed in fluid communication with a portion of the first portion of the implant; and

wherein the second actuator includes a draw bar configured to exert an axial load to the second portion of the implant.

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